

GLOBAL HEALTH SUPPLY CHAIN MANAGEMENT: LESSONS LEARNED AND WAYS FORWARD

HEARING

BEFORE THE

SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH,
GLOBAL HUMAN RIGHTS, AND
INTERNATIONAL ORGANIZATIONS

OF THE

COMMITTEE ON FOREIGN AFFAIRS
HOUSE OF REPRESENTATIVES

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GLOBAL HEALTH SUPPLY CHAIN MANAGEMENT: LESSONS LEARNED AND WAYS FORWARD

THURSDAY, MAY 17, 2018

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH,
GLOBAL HUMAN RIGHTS, AND INTERNATIONAL ORGANIZATIONS,
COMMITTEE ON FOREIGN AFFAIRS,
Washington, DC.

The subcommittee met, pursuant to notice, at 1:00 p.m., in room 2172 Rayburn House Office Building, Hon. Christopher H. Smith (chairman of the subcommittee) presiding.

Mr. SMITH. The hearing will come to order, and good afternoon.

I want to thank you all for being here, especially our two very distinguished witnesses.

There will be a couple of breaks. Unfortunately, we have some votes coming up very shortly, but we will stay at it because this is an extremely important issue, and I want to thank you for the work that you have done.

By holding today's hearing, this subcommittee is fulfilling a very important obligation to the American taxpayers to conduct vigorous oversight of our global health programs in order to ensure that U.S. taxpayer dollars are being used properly and efficiently to deliver the aid to rightful beneficiaries. It also, we hope, will help better the lives of those beneficiaries in the developing world who receive lifesaving medications thanks to the generosity of the American people.

Specifically, we will address serious concerns regarding the United States Agency for International Development's contractor selection process and performance by the supply chain management company Chemonics International, which was awarded the agency's largest ever monetary contract, a contract with a ceiling of \$9.5 billion over 5 years. Congressional interest in this was triggered by reports last year that Chemonics had failed repeatedly to deliver essential health commodities in a timely manner to African and other countries where they are desperately needed, most critically, antiretrovirals to treat HIV/AIDS patients. At its lowest point, only 7 percent of deliveries were made on time and in full. The purpose of this hearing is to determine where USAID went wrong in the selection and transition process of this contractor and what could be done to preclude such a failure in the future.

In January 2014, USAID issued a request for proposals for a supply chain management contractor that would consolidate procurement and delivery of health commodities to Africa and elsewhere as well as provide health systems strengthening in conjunction with the President's Emergency Plan for AIDS Relief, or PEPFAR. Two companies responded to the request, the first being the then-existing contractor, Partnerships for Supply Chain Management, and the second being Chemonics. In April 2015, USAID awarded the contract to Chemonics, in large part because Chemonics displayed greater data visibility, or they purportedly did, and IT capability. As might be expected, the incumbent losing bidder filed a complaint against USAID with the U.S. Government Accountability Office and, upon losing that, lodged an appeal with the U.S. Court of Federal Claims. In both instances, the differential standard of review was applied and, thus, USAID's decision was upheld.

Following the final decision, the Partnership began this process to transition services to Chemonics. While tensions between the two companies were evident throughout the transition process, performance levels remained steady until after Chemonics fully took over the operations. At the end of 2016, under Chemonics' leadership, on-time deliveries dropped from 84 percent to 67 percent. They continued to free fall throughout 2016, down to 31 percent, and then, reaching an all-time low of 7 percent in the first quarter of 2017.

During this time, some countries reported stockouts of some of these lifesaving commodities. This absolutely is unacceptable, and this unacceptable delivery record resulted in part from poor data quality, weak inventory management and distribution practices, and poor planning.

However, while hindsight is 20/20, one can question what justified some of the assumptions USAID made when it selected Chemonics. For example, USAID has graded Chemonics' data visibility as "excellent," placing great reliance on Chemonics' promises regarding an IT system. No demonstration of a functioning IT system was ever requested by USAID during the selection process, however, nor in any in-person presentation during which the technical evaluation committee could have asked questions.

Indeed, no such demonstration could have taken place since Chemonics had not even completed building the IT system that was specifically required in the request for the proposals. The system would not be fully functional until June 2017, nearly a year and a half after Chemonics began operations.

While USAID did require a corrective action plan for Chemonics and implemented some corrective measures on the company, including freezing promotions and raises until performance reached an acceptable level, it is the spur of congressional oversight, including visits in the field, which has forced the issue and brings us to where we are today, demanding answers and seeking viable solutions.

Our oversight continues to raise questions, and not only with respect to the implementing partner, but also how PEPFAR and USAID are coordinating their activities. We need to know how it is that each year PEPFAR engages partner nations in developing country operation plans designed to meet particular needs of each

nation while guaranteeing that annual taxpayer investments are maximally focused and traceable for impact.

Yet, USAID is still paying for the drug Nevirapine to give to HIV patients in Africa. Nevirapine is an outdated drug with serious side effects that was supposed to have been retired long ago. This is an issue, hopefully, our witnesses can speak to and give us some insight into it.

I would also ask that our witnesses not only do a postmortem of what went wrong, speak to the mistakes that were made, but also provide solutions and a way forward, because I know both of you are completely committed to this. And we are very grateful that you took the time to be here with us.

Okay. I would like to now begin with our introduction of the witnesses, beginning with Ambassador Deborah Birx, who is a coordinator for the United States Government activities around HIV/AIDS and U.S. Special Representative for Global Health Diplomacy. Over her 30-year career, she has focused on HIV/AIDS immunology, vaccine research, and global health. Ambassador Birx oversees the implementation of the U.S. President's Emergency Plan for AIDS Relief and all U.S. Government engagement with the Global Fund to Fight AIDS, tuberculosis, and malaria. In her role as U.S. Special Representative for Global Health Diplomacy, she works to align the U.S. Government's diplomacy in foreign assistance programs that address global health challenges and move forward in achieving those goals, eliminating AIDS and preventable child and maternal deaths, and combating infectious disease threats.

This committee has worked very closely with the Ambassador for years, and I laud her tremendous contributions to these lifesaving interventions during her whole career, but especially, as I have gotten to know her, in the work here.

Then we will hear from Irene Koek, who is a Senior Deputy Assistant Administrator in USAID's Global Health Bureau. Previously, she was the Senior Infectious Disease Advisor for the Global Health Bureau and the Global Health Security Agenda, led at USAID. From 2010 to 2014, she was Director of the Health Office in USAID in Indonesia, where she served as Health Attache and PEPFAR Coordinator. During her 32-year career with USAID, Ms. Koek has also worked as a Health Advisor to the Policy Program Coordination Bureau and as Chief of the Infectious Disease Division in the Global Health Bureau, helped start the President's Malaria Initiative, and served as chair of the Stop TB Coordinating Board. Ms. Koek has a master's of arts degree from George Washington University.

Madam Ambassador, if you could give your testimony?

STATEMENT OF THE HONORABLE DEBORAH L. BIRX, M.D., U.S. GLOBAL AIDS COORDINATOR, U.S. SPECIAL REPRESENTATIVE FOR GLOBAL HEALTH DIPLOMACY, U.S. DEPARTMENT OF STATE

Ambassador BIRX. Thank you. Thank you, Chairman Smith, and recognizing Ranking Member Bass and other distinguished members of the subcommittee. I am really deeply honored to be here before this subcommittee of the House Foreign Affairs Committee,

mostly because of the amazing visionary support this committee has provided to PEPFAR since its inception.

Today, more than 14 million men, women, and children are alive, and we have transformed the global HIV/AIDS pandemic because of the compassionate commitments of members of this subcommittee and the full committee, and also, the bipartisan, bicameral support of your congressional colleagues. Under the leadership of President Bush, President Obama, and President Trump, and, of course, the generosity of the American people, we have made amazing progress.

All Americans should be immensely proud of PEPFAR's achievements because they are their achievements. PEPFAR achievements have been made possible really for two very specific reasons. First, through our collective unrelenting focus on outcomes and impacts and using data to improve all aspects of HIV prevention and treatment services. And secondly, through our absolute commitment of using the best of each U.S. Government agency to achieve more each year through increased efficiencies and effectiveness.

This month marks the 15th anniversary of PEPFAR's establishment. With strong bipartisan leadership, the U.S. Government is not only saving lives, but we are accelerating our global impact and changing the very course of this pandemic.

A principal factor in our success is that we harvest the latest science and data to direct resources where the HIV/AIDS pandemic is the largest, where the need is greatest, and then, to ensure that the resources that are placed there are used as effectively as possible for the greatest impact of U.S. taxpayer dollars invested. Each quarter, we look rigorously at our outcomes and costs in order to continuously improve our work. This commitment to transparency and accountability and impact is why PEPFAR is often cited as one of the most effective and efficient U.S. foreign assistance programs in history.

PEPFAR has invested billions toward building and supporting national health systems, including over \$3 billion in the last 9 years for a strong, reliable, and secure supply chain. A high-performing supply chain is the lifeblood of our work. We must ensure that the right commodities reach the right people in the right places at the right time. This requires effective and efficient commodity forecasting, procurement, and delivery, including tracking every product all the way down to the site level where it is provided to the patient.

PEPFAR has not only invested billions in strengthening supply chain, but also continues to provide ongoing technical assistance to governments and non-governmental supply chains, building infrastructure, and funding hundreds of full-time U.S. Government personnel in-country and within governments. We are driven every day to bring the best medicines, the best diagnostics, and the best monitoring to every client we serve.

After all this work that we have done together to bring the best, we are totally dependent on the last step. The supply chain must deliver, and deliver optimally every day everywhere.

Mr. SMITH. Ambassador Birx—

Ambassador BIRX. Yes?

Mr. SMITH. If you wouldn't mind, there is a vote being called right now.

Ambassador BIRX. It is a perfect stopping point.

Mr. SMITH. So, it seems rude as can be, and I apologize for it, but we will take a brief recess for the vote. My understanding is that several members will be coming back, including the ranking member.

Your opening was outstanding and you are only halfway through it, but maybe some of that could be reiterated again for the members when they do arrive because it is important.

Ambassador BIRX. Perfect.

Mr. SMITH. So, we stand in brief recess pending the vote.

[Recess.]

Mr. SMITH. The subcommittee will resume its sitting.

Again, please accept my apologies for that extraordinarily long delay. You are very patient, and I thank you for that patience.

We have been joined by both the ranking member, Karen Bass, but also our distinguished chairman, Ed Royce. So, the chairman is recognized.

Mr. ROYCE. I thank the chairman.

And I also thank Ambassador Birx and Deputy Administrator of the USAID, Irene Koek. Thank you very much for being with us today.

I would just mention how essential to our U.S. interests, how critical to our interests your work is. I think it is also essential to the well-being of people around this planet and certainly every American. Because if you think through the consequences, that effort helps us combat deadly infectious diseases certainly. We think about Ebola and pandemic flu and the effort necessary to take those down in the early stages, and at the same time these invisible enemies respect no boundaries, obviously. They threaten not only people around this globe, they threaten our economic growth, our prosperity.

So, it advances global efforts to certainly eradicate polio and eradicate other debilitating diseases, and it promotes maternal and child health. It advances, as I said, U.S. economic interests, certainly our security interests. I think it also helps grow stable societies.

I did want to go on the record here and say something about those efforts, efforts that buy us an awful lot of goodwill, and efforts, frankly, that have saved the lives of millions of men and women and children, and do so each and every year.

The overwhelming majority of U.S. global health commodities, including for medicines and other products, are delivered through USAID-managed procurement and supply management contract, or PSM, and they deliver commodities in 56 countries. They provide related technical assistance to 40 countries. In January 2016, USAID combined two prior PSM contracts into one with a 5-year, \$9.5 billion ceiling. This is the largest contract that USAID ever managed. Last fall, this committee began receiving reports of stockouts, and that is why we hold the hearing today with our oversight efforts. Those stockouts were lifesaving ARV drugs and bed nets that were meant to be delivered under the megacontract.

So, I would just like to commend Chairman Smith here for his leadership and, also, Karen Bass, the ranking member of this committee, because, in response, the investigation that was launched by our committee included a review of thousands of pages of contract agreements and guidelines and various orders and notifications. They conducted dozens of interviews with USAID, with CDC, with current and past supply chain managers, and local implementing partners. Staff traveled to Uganda, I know, and to Ethiopia. I know the members here traveled extensively on this.

Wherever significant disruptions were reported, they met with USAID mission staff and local implementers, and even inspected warehouses and identified the challenged. Through this investigation, we have found that at the lowest point the on-time, in-full delivery rates for lifesaving HIV/AIDS medicines was a very shocking number. It was 7 percent, reportedly, while industry standards is around 70 percent. Delays were caused by mishaps at many stages of the process, from the contract-awarding process to the transition between the contractors, to delays in the implementation of new, supposedly highly regarded IT systems, to the performance of the contractor, and the oversight of USAID and the Office of the Global AIDS Coordinator.

While delivery rates have improved and reports of stockouts have ceased, concerns about what went wrong and why remain. That is, again, the focus here. So, we continue our oversight of USAID and the Office of Global AIDS Coordinator to identify lessons learned and to ensure that these mistakes are not repeated. We recognize that Administrator Green and Ambassador Birx inherited this contract from the previous administration, and I applaud them for their dedication and rigorous work toward righting the situation here.

In global health programs, no amount of mismanagement or waste can be tolerated because lives are literally on the line. So, we have got to get it right.

I want to thank again Chairman Smith and Karen Bass for their efforts to get it right. And I thank you, too, for your efforts in this regard.

With that, I would like to yield back, Mr. Chairman.

Mr. SMITH. Thank you very much, Mr. Chairman, and thank you for your ongoing work on this important—I mean, oversight is a very important part of our work.

Mr. ROYCE. Thank you.

Mr. SMITH. And you certainly have done an outstanding job. So, thank you.

Mr. ROYCE. Thank you.

Mr. SMITH. I would like to now yield to our distinguished ranking member, Ms. Bass.

Ms. BASS. Well, thank you, Mr. Chair and Mr. Chair, for your leadership on this issue and for holding today's hearing.

This is one of those cases where we get to see how U.S. Government programs are working abroad. From what we have here in Congress, there have clearly been some challenges. I look forward to hearing from the witnesses how these challenges have been addressed. In August 2017, news reporting revealed that \$9.5 billion in the global health supply chain, funded by USAID, was failing to

deliver an acceptable percentage of its shipments on time and in full. Not long after that article, Members of Congress started to get calls from various groups reporting that antiretroviral medications were not available. Imagine our disbelief when people were reporting low levels of medication or complete stockouts, when we here in Congress knew that the money was available.

While Chemonics International, the project implementer, has acknowledged that there were challenges and described steps the company has taken to improve performance, it is important to reflect on the fact that the project coordinates a global health supply chain for commodities such as HIV tests and treatments. And I understand that there has been some rectification of the situation, but I guess, for me and what I really would like to understand, how a company as big as that, that has been in the business as long as this, got into this problem in the first place. I do think that it takes a lot of courage for someone to take that first step, if you potentially have HIV, to get tested. But imagine hearing that the test or the medications are not available.

The same holds true for malaria drugs. So, this supply chain supports the U.S. Government's largest and most important global health initiatives, including the PEPFAR, the President's Malaria Initiative, and population and reproductive health programs. I am very concerned that, after 15 years into PEPFAR, we are having to have a hearing to address low performance and other problems with the supply chain project that coordinates lifesaving commodities.

Needless to say, this raises serious concerns here in Congress. Our role, of course, is oversight, and it is to see how that money is being spent and to ensure that the contractor is performing adequate, but, more importantly, PEPFAR, the President's Malaria Initiative, and other U.S.-led global health programs save millions of lives. What we want to do here is understand what happened in order to make sure that it doesn't ever happen again.

In addition to mentioning that—I know that there has been some rectification of this—I want to understand just in the contracting process, if I am a company and I don't deliver, am I still getting paid? I would like to understand that. If so, what kind of accounting, what kind of records? How does this happen that the company actually doesn't raise alarm to say, "We are having difficulty. Such a small percentage of what we are supposed to deliver is being delivered. We are not getting paid. We need the money." It would be deeply disturbing to think that we are not delivering the product, but we are still getting paid.

I yield back.

Mr. SMITH. Thank you, Ranking Member Bass.

Mr. Garrett?

Mr. GARRETT. Thank you, Mr. Chairman.

As a precursor to the comments of the distinguished panel, I would submit that mismanagement and waste in global health programs transcends even that which was very astutely and accurately pointed out by my colleague and chairman of the full committee, Congressman Royce. He said, global health programs matter so much because mismanagement and waste actually costs human lives. And he is absolutely correct. However, the other thing

that mismanagement and waste does is create a paradigm wherein those people in this body, which under Article I of the United States Constitution are responsible for creating budgets, it makes it really hard for us to tell the taxpayers that we are doing our job well.

And I have not a long history because I have only been here for 16 months, but a pretty daggone outspoken history of advocating on behalf of foreign aid and expenditures. So, I support foreign aid and expenditures, but I can't support waste, which is why this hearing is so important.

And Congresswoman Bass said, accurately—and I again commend her because one of the neat things about Foreign Affairs is we actually get to be bipartisan here—that our role is oversight. Absolutely true, but our role is oversight and the responsible stewardship and allocation of tax dollars taken from working Americans.

Now am I advocating against these efforts? Absolutely not. In fact, while I could think of many things to say about, for example, the George W. Bush administration, some good and some bad, during my small amount of time on the African continent, I heard a lot of glowing reviews by virtue of this nation's investment in Africa, in humanitarian aid, and specifically in HIV and AIDS. And these are good things because what they do is they create a vision of the world that is different from that which they see from Hollywood, which is philanderers, car chases, and drug-related shootouts, right?

So, we can do good, but the oversight element is so important because the fiscal conservatives want to cut where they can. And I understand that. If I can't say we are being good stewards of these funds, how can I justify the continued expenditure? And because I genuinely believe, not only as a Member of Congress, but as someone who wore the uniform of the United States military, that if we can create a view by the individuals in the emerging world particularly of the United States as a benevolent partner, as opposed to a dictatorial hegemonic power, then better things will happen and more lives will be saved.

So, I commend the subcommittee chairman, my colleagues Ms. Bass and Mr. Royce, on their absolutely spot-on words. I would just take it a step further and say we have a responsibility to be good stewards. In order for us to be able to sell, if you will, the idea that foreign aid matters and works, we have got to get this right.

Thank you, and I would yield back.

Mr. SMITH. Thank you very much.

Ambassador Birx, if you wouldn't mind starting from the top? Because we really want to hear what you have got to say.

Ambassador BIRX. Thank you. Thank you, Chairman Smith.

It is a privilege to be here with Ranking Member Bass. We spent some time together in Malawi and Kenya and really had an extraordinary trip.

And I really want to recognize Chairman Royce for the support that he has given to PEPFAR.

I also want to recognize the staff because the dialog that we constantly have with your staff has made the program stronger.

In answering, and just to note, I was also active duty military for 29 years. I appreciate deeply your comments because that is what this is about. This is about the translation of the generosity and the commitment of the American people to envision a better world for everyone. And to be part of that has been a true privilege.

Today, more than 14 million men, women, and children are alive and their lives have been transformed because of HIV/AIDS response from the U.S. Government, really because of the compassion and commitment of the American people and the people of this subcommittee, the main committee, and the bipartisan, bicameral support that we have had for the 15 years of PEPFAR.

We have also had administration support from President Bush to President Trump, and President Obama in between, really continuous support across the aisle for this important program. Why? Because we have been focused on impact and results and transparency and accountability to really ensure that every dollar that the U.S. taxpayer entrusts with us is spent effectively and efficiently.

PEPFAR's accomplishments have been possible for two fundamental reasons. One, we are unrelenting in our data analysis and ensuring that we understand what is happening at the sites where the clients are being served. Secondly, an absolute commitment to utilize the whole of government approach, utilizing the best of each U.S. Government agency to achieve more each year through more effectiveness and efficiency.

Today, and, indeed, in a couple of hours across in Dirksen, we recognize the 15th anniversary of the PEPFAR establishment by Congress, from the State of the Union of President Bush in January. This bipartisan leadership is not only saving lives, but now we are changing the very course of this pandemic.

A principal factor in our success is we are harnessing the latest data and the latest science, and directing those resources where the HIV epidemic is the largest, the need is greatest. And then, ensuring those resources are effectively and efficiently spent, so that we have the maximum impact for each dollar investment.

We look at this data carefully every quarter, looking at outcomes and costs, and in order to continuously improve our work. This commitment to transparency and accountability and impact is why PEPFAR is cited as one of the most effective and efficient U.S. foreign assistance programs in history, but, importantly, is also transforming lives around the world, as you have witnessed in Africa.

PEPFAR has invested billions into the health systems, including over \$3 billion to a strong, reliable, and secure supply chain. As Representative Bass just mentioned, how is this happening 15 years in with these large investments? A high-performing supply chain is the lifeblood of our work. We must ensure that the right commodities reach the right people in the right places at the right time. This requires efficient and effective commodity forecasting, procurement, and delivery, and tracking every product down to the site where the client needs the medications or the diagnosis.

PEPFAR has not only invested billions in strengthening this supply chain, but continues to provide technical assistance to governments and non-governmental supply chains, building infrastructure, funding hundreds of full-time U.S. Government personnel in-

country and within government. We are driven every day to bring the best medicines and the best diagnostics and the best monitoring to every client we serve. All of this work to bring the best is totally dependent on the last step, ensuring that the supply chain is functional at every aspect down to the clients we serve.

So, I have been deeply concerned about the recent supply chain challenges that bring us here today. Some of the issues have been fixed and markedly improved. Others still need to be urgently addressed, and some of them have been urgently addressed just in the last week, including the Nevirapine issue.

Everyone who is involved in the supply chain at all levels must feel the same sense of accountability to get our successful drugs and medications to the levels that they need to be everywhere along the chain. We need it to successfully and sustainably deliver these essential lifesaving treatments and commodities for mothers, fathers, sisters, brothers, sons, and daughters that we have all been privileged to serve for the last 15 years, because they deserve nothing more than our best and we can and must do better.

That is why I have strengthened the State Department's oversight of all PEPFAR-supported commodities. This includes monthly antiretroviral risk reporting, increased oversight of the Emergency Commodity Fund's use and expenditures, approval over all procurements of any legacy ARVs that are no longer considered first-line, and, critically, sharing the commodities-related data between PEPFAR, USAID, and the Global Fund.

Late deliveries have consequences. No one wants to be down to their last test kit when a pregnant mother walks through the door and needs to be tested. So, every clinic, every district hospital, and every community site begins to slow down services when they have a concern about the arrival of commodities and drugs. People are turned away and services are not delivered when people are concerned about commodity stocks.

Together we are closer than ever to controlling this pandemic and decreasing the future cost because of effective and focused programming. What once seemed impossible is now possible, controlling and ultimately ending the AIDS epidemic as a public health threat for all of us around the globe. But this will only happen if we constantly hold ourselves accountable to not only do more, but to do it better. We all need to be at our best every day, and everyone who is a part of PEPFAR needs to be at their best. And every contract needs to deliver its best every day.

Chairman Smith, Ranking Member Bass, and the other distinguished members of this subcommittee, thank you for this opportunity to hear from each of you today. Thank you for your continued support, your staff's support. And we are at once profoundly grateful for the work that you have done to ensure that PEPFAR is successful every day.

I look forward to your questions.

[The prepared statement of Ambassador Birx follows:]

Written Testimony
Ambassador-at-Large Deborah L. Birx, M.D.
Coordinator of the United States Government Activities to Combat
HIV/AIDS and
U.S. Special Representative for Global Health Diplomacy
House Foreign Affairs Committee
Subcommittee on Africa, Global Health, Global Human Rights, and
International Organizations
“Global Health Supply Chain Management: Lessons Learned and
Ways Forward”

May 17, 2018

Thank you Chairman Smith, Ranking Member Bass, and other distinguished members of this Subcommittee. I am deeply honored to appear before the House Foreign Affairs Committee and your Subcommittee, which have provided such visionary leadership and remarkable support for the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) since its inception in 2003.

Today, more than 14 million men, women, and children are alive and we have transformed the global HIV/AIDS pandemic because of the compassion and commitment of the members of this Subcommittee and the full House Foreign Affairs Committee; the bipartisan, bicameral support of your congressional colleagues; the leadership of President George W. Bush, President Barack Obama, and President Trump; and the generosity of the American people. All Americans should be immensely proud of PEPFAR's achievements – because they are also their achievements.

PEPFAR's achievements are made possible because of two reasons. First, through our collective, unrelenting focus on outcome and impact results - using data to improve all aspects of HIV prevention and treatment services. And second, through our absolute commitment to using the best of each U.S. government agency to achieve more each year through increased efficiency and effectiveness.

This month, alongside our many partners, we are marking the 15th anniversary of PEPFAR's establishment, which is officially on May 27th. With strong bipartisan leadership, the U.S. government, through PEPFAR, now supports lifesaving HIV treatment for more than 14 million people. We have enabled more than 2.2 million babies to be born HIV free to HIV-positive mothers and assist more than 6.4 million orphans, vulnerable children, and their caregivers to ensure the next generation can thrive. We have trained nearly 250,000 new health care workers to deliver HIV and other health services. Our efforts have also reduced new HIV diagnoses by 25-40 percent among adolescent girls and young women in 65 percent of the highest-HIV-burden communities implementing our DREAMS (Determined, Resilient, Empowered,

AIDS-free, Mentored, and Safe) public-private partnership in 10 of the highest-HIV-burden African countries since 2015.

The United States is not only delivering results, but also accelerating our global impact against the HIV/AIDS epidemic, as articulated in the Administration's PEPFAR Strategy for Accelerating HIV/AIDS Epidemic Control (2017-2020). PEPFAR-funded Population-based Health Impact Assessments show that up to 13 high-HIV-burden countries are poised to achieve epidemic control by 2020. PEPFAR's efforts in these 13 countries, in partnership with host-country governments and the international community, will produce a roadmap to reach epidemic control in the more than 50 countries where PEPFAR works. For example, Ethiopia is within months of reaching HIV/AIDS epidemic control and we have been able to reduce U.S. assistance through PEPFAR in the country substantially – from more than \$300 million in FY 2010 down to nearly \$70 million requested in FY 2019 due to this success. Sustaining or maintaining epidemic control into the future will cost much less than what was needed to achieve it.

We have come a long way in the global HIV/AIDS response in the 15 years since PEPFAR began. In 2003, an HIV diagnosis was a death sentence in many countries, and entire families and communities were falling ill. In some African countries, infant mortality doubled, child mortality tripled, and life expectancy dropped by 20 years, with millions of orphans left behind on the continent. At that time, only 50,000 people were on lifesaving HIV treatment in Africa.

A principal factor in PEPFAR's success: we harness the latest data and science to direct resources where the HIV/AIDS epidemic is the largest, the need is highest, and they are most efficiently used to have the greatest impact per each dollar invested. Every quarter we look rigorously at our outcomes and costs in order to continuously improve our work. This commitment to transparency, accountability, and impact is why PEPFAR is often cited as one of the most effective and efficient U.S. foreign assistance programs in history.

PEPFAR in-country teams assess populations and geographies, design interventions, and set targets aimed at accelerating epidemic control based on the clarity provided by the data. This allows the program, in partnership with governments and communities, to focus services, stop or improve the activities that are not having the desired outcomes, and expand those activities that are reaching essential groups. To enhance the systematic gathering, analysis, synthesis, and interpretation of program data for routinely measuring progress, PEPFAR has a robust set of Monitoring, Evaluation, and Reporting program indicators that collect site-level programmatic results by age (in five-year age bands), sex, and, in some cases, key population for each person receiving PEPFAR-supported services, which are reviewed at least quarterly.

In addition to using data to target our efforts toward saving and improving the lives of millions of people living with and affected by HIV/AIDS, PEPFAR has invested to enhance surveillance and health information systems as well as laboratories that are critical to effective and efficient health care delivery. In 2017 alone, through PEPFAR's

Country and Regional Operational Plans (COPs/ROPs), we invested nearly \$600 million in horizontal, above-site health system strengthening investments. This includes nearly \$100 million to enhance laboratory systems and almost \$70 million to strengthen supply chains.

Over the past 15 years, through these types of health systems strengthening investments, PEPFAR has enhanced global health security, accelerating the progress toward a world more secure from the threat of infectious diseases by improving the global capacity to prevent, detect, and respond to new and existing risks. PEPFAR's investments in countries with sizable HIV/AIDS burdens have also bolstered their ability to swiftly address Ebola, avian flu, cholera, and other outbreaks, which ultimately protects American lives and America's national security.

Through harnessing the whole-of-government approach, PEPFAR has been able to bring the most effective, state of the art antiretroviral agents, diagnostic and monitoring commodities to the most resource limited settings utilizing the brilliant research from the U.S. National Institutes of Health, the strength of the U.S. Food and Drug Administration, and working effectively with manufacturers translating science to patients in record time.

PEPFAR has invested toward building and supporting a strong, reliable, and secure supply chain to serve the more than 50 countries where we work. A high-performing supply chain is the lifeblood of our efforts. We must ensure that the right commodities reach the right people, in the right places, and at the right time. This requires effective and efficient commodity forecasting, procurement, and delivery – including tracking every product all the way down to the site-level where it is provided to the patient. PEPFAR has invested billions since 2003 on strengthening the supply chain – providing technical assistance to Government and non-Governmental Supply chains, building infrastructure, and funding hundreds of fulltime U.S. government personnel in-country and with host governments. Collectively, we have worked together to achieve amazing progress and we remain committed to bringing the most effective medications to those that need it.

This is why I am deeply concerned about the recent supply chain challenges that bring us here today. Suffice it is to say, there are a number of things that have not gone well in this regard. Some of these have been fixed but others still need to be urgently addressed. Everyone who is involved in the supply chain at all levels must feel a strong sense of accountability to get our supply chain on the right track. We need it so we can successfully and sustainably deliver the essential lifesaving treatment and other commodities for the mothers, fathers, sisters, brothers, daughters, and sons who we are so privileged to serve. They deserve nothing less than our best, and we can do better. After PEPFAR's significant investment as well as our substantial U.S. government in-country and technical support, we should not be at this place in this moment.

In light of these serious supply chain shortcomings, I have instituted strengthened headquarters oversight on all PEPFAR-supported commodities. This includes – but is

not limited to – monthly antiretroviral medication (ARV) risk reporting; approval of the Emergency Commodity Fund to address potential, or existing, stock outs; approval over the procurement of any legacy ARVs using funds approved in PEPFAR 2017 or 2018 Country Operational Plans; and sharing of commodities-related data between PEPFAR, USAID, and the Global Fund to Fight AIDS, Tuberculosis, and Malaria. Further, I have initiated rigorous PEPFAR-wide partner management to increase performance and efficiency.

Moving forward, PEPFAR now tracks and analyzes its results and partner performance data down to the site level at least on a quarterly basis as opposed to previous practice, which was annually or semiannually. We can now identify and address emerging problems earlier, allowing for more rapid course-correction before these problems become big ones. Our partner performance and our programmatic outcomes and impact are critical to the successful functioning of the supply chain and the absolute predictability of supplies. No one wants to be down to their last test when a pregnant woman comes through the door; in such a situation, every clinic, district hospital and community site of service begins to slow down their outreach and testing to ensure adequate supplies. With the breadth and depth of our investment over the years, we should expect nothing less than a highly functioning and sustainable supply chain.

We are not only collecting our results and partner performance data every quarter, but also sharing it with the public. Last month we reached a new transparency milestone by publicly releasing program results and implementing partner performance for more than 40,000 PEPFAR-supported facilities spanning all of our 35 country and regional programs. By putting all of these data online, we hope that everyone will be more empowered to effectively and sustainably control the epidemic.

One of the most important tasks that our programs and our supply chain must soon navigate is the transition to new and more effective antiretroviral regimens based on Dolutegravir (DTG), a new integrase inhibitor. Dolutegravir is cheaper, better tolerated for the patient, and leads to improved results including faster viral suppression. There is a virtuous circle created by DTG's low side effect profile, which makes adherence easier. It also offers easier adherence and fewer side effects for most of the population, although a full analysis of the safety in pregnant women is still being explored. The transition to DTG will mean a more rapid adoption of differentiated care and more models of community care. It will be critical to utilize and move rapidly to regimens that are more effective and better tolerated, especially as we start treatment on clients who are early in the progression of the disease and still feeling well, to ensure people stay on their treatment. We need a supply chain supplier that is nimble and proactive.

Due to faster viral suppression, ART prevention benefits are also felt quicker with the use of DTG. The drug's wide applicability – including for patients currently on second-line regimens – simplifies supply chain regimes. It also creates very low resistance, which should allay concerns that the increase number of people on ART could lead to the rise of drug-resistant strains of HIV.

In our 2018 PEPFAR Country Operational Plans, which I approved last month for 22 countries, we worked with each of them to develop a transition plan to Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate (TLD), including the utilization of so-called "legacy ARVs" to prevent stocks out as this transition takes place. Taken together, these transition plans have allowed us to develop a global forecasting tool to ensure that future TLD demand does not outpace product supply. This positions our supply chain to account in advance for manufacturing lead times and product availability, and to establish delivery timelines that support effective and efficient program performance. It allows us to be proactive and obtain the best prices.

In addition to transitioning to new and more effective commodities, PEPFAR is also working to lower the costs of other purchases, most notably the cost of laboratory reagents. For example, PEPFAR has achieved impressive reductions in the cost of viral load tests, in some cases from \$40 per test to as low as \$15. Further future reductions are possible. In addition, with fewer clinic visits, fewer laboratory tests are needed as PEPFAR works hard to eliminate unnecessary tests. In fact, with Test and Start, CD4 counts are no longer necessary to determine the initiation of ART. PEPFAR is scaling back support to CD4 testing, which is generally needed in fewer cases, freeing up resources for the expansion of viral load monitoring to ensure clients remain virally suppressed.

Together, we are closer than ever to ending AIDS and decreasing the future costs of addressing the pandemic because of effective and focused programming. What once seemed impossible is now possible – controlling and ultimately ending the AIDS epidemic as a public health threat. But this will only happen if we all constantly hold ourselves accountable to not only do more but also do it better.

Chairman Smith, Ranking Member Bass, and other distinguished members of this Subcommittee, thank you for the opportunity to appear before you today. We are once again profoundly grateful for the ongoing support and engagement of the House Foreign Affairs Committee and this Subcommittee for PEPFAR's work.

Thank you. I look forward to your questions.

Mr. SMITH. Thank you very much.
And, Ms. Koek?

**STATEMENT OF MS. IRENE KOEK, SENIOR DEPUTY ASSISTANT
ADMINISTRATOR, GLOBAL HEALTH BUREAU, U.S. AGENCY
FOR INTERNATIONAL DEVELOPMENT**

Ms. KOEK. Thank you very much. Thank you, Chairman Smith, Ranking Member Bass, distinguished members of this committee. And I would also like to thank Chairman Royce for joining us here today.

And I want to thank you very much for the very strong support and leadership you provided to the work the U.S. Government does in global health. I would also like to thank you for the oversight and the oversight role that this committee plays, and again, echo Ambassador Birx's thanks not only to you, but also to the staff for the engagement over these last many months. We very much appreciate that.

I do appreciate this opportunity to discuss USAID's work in supply chain management and commodity procurement, to talk about the procurement process we use, provide an update on the performance of the contract, and share our plans for the path forward.

For decades, USAID has been a world leader in providing essential lifesaving commodities for public health programs. We manage global health commodity procurement and delivery on behalf of the interagency PEPFAR and the U.S. President's Malaria Initiative, or PMI, and many of USAID's global health programs. For example, this work has helped keep the 14 million patients on antiretroviral therapy that Ambassador Birx mentioned and delivers malaria prevention, treatment, and controlled commodities that benefit over half a billion people across Africa. The success of the U.S. Government's global health programs has depended on our investments to ensure the availability of health products in the countries where we work.

Previously, USAID's procurement and supply chain operations were managed under two large contracts, one for HIV and one for other health programs, including PMI. In 2012, we began the process to design a follow-on program seeking to incorporate lessons we had learned from the predecessor projects, increase efficiencies, and continue to identify cost savings. We solicited input from headquarters and field staff, from the Office of the Global AIDS Coordinator, from PMI, from the Centers for Disease Control and Prevention, and other partners. We commissioned an independent expert review of existing supply chain models to ensure we applied state-of-the-art and commercial sector supply chain best practices.

Because of the heavy management burden in the field and to prevent or minimize duplication of systems, we made the decision to consolidate procurement and supply chain function into one large award, rather than two. We recognized that any transition of this size carried risks. We took steps to mitigate the risk of supply interruptions and stockouts by increasing inventories and ensuring overlap between the prior contracts and the new contracts, all in order to ensure that patient access to commodities would continue smoothly.

Based on the extensive evaluation of the proposals by a review panel which include USAID and Office of the Global AIDS Coordinator's staff, USAID awarded the contract in April 2015 to a 12-member consortium led by Chemonics International. This consortium includes world leaders in supply chain, including IBM and Kuehne & Nagel. Work began in January 2016 after a protest to the GAO and claim to the Court of Federal Claims were decided in USAID's favor.

The contract faced management challenges in the initial months and had poor performance in its on-time delivery. USAID staff identified these performance issues very early in the process. In Washington and in the field, we have worked to minimize the impact of late deliveries, including assisting in the redistribution of commodities between facilities to prevent stockouts.

We have also held the contractor accountable. In response to USAID's demands for improvements in April 2017, Chemonics developed and implemented an action plan to address its deficiencies. As a result, we have, indeed, seen significant improvement in their overall on-time delivery and performance.

The most recent data show that on-time delivery increased from 31 percent to 73 percent over the past 6 months. On-time and full delivery also improved from 32 percent to 67 percent over that same period. The backlog of undelivered orders is now under 5 percent of total shipments in industry standard.

While these improvements have been sustained, even as order volume has increased, progress must continue. Performance has not yet met the target for on-time delivery, and USAID continues to provide a high level of oversight and scrutiny over this contract to hold Chemonics accountable.

We have started to aggressively apply lessons learned from this experience to the design of USAID's next supply chain programs. Building on USAID's broader procurement reform efforts, we are identifying ways to be innovative in our design of procurement and management of awards and effectively manage risk. We will actively engage industry leaders, interagency partners, and the field throughout this process. We will also build in the opportunities for public comment, sharing the design process, and closely consult with this committee and our other oversight committees.

USAID's highest priority is to ensure that patients can access critical health products that prevent and treat life-threatening disease and that there is no interruption in treatment. We take our obligation to ensure good stewardship of taxpayer resources very seriously.

Thank you for your attention to this very important issue, and I look forward to answering your questions.

[The prepared statement of Ms. Koek follows:]

Testimony of USAID Senior Deputy Administrator, Bureau for Global Health, Irene Koek
before the House Foreign Affairs Committee; Sub-Committee On Africa, Global Health, Global
Human Rights, and International Organizations

Thursday, May 17, 2018

Introduction

Thank you, Chairman Smith, Ranking Member Bass, Members of the Subcommittee. I appreciate this opportunity to discuss the U.S. Agency for International Development's (USAID's) work to ensure critical, life-saving medicines and health supplies reach intended recipients in a secure, timely, and cost-efficient manner.

Around the world, health workers, whether community or facility-based, are the first line for public health, as they provide testing and treatment for malaria, distribute treatments for other childhood diseases, and fill prescriptions for anti-retroviral medicines (ARVs) for people who are living with HIV. The health successes of the networks of these health workers depend on the effectiveness of the supply chains that procure and distribute diagnostic materials, medicines, and key health commodities. A well-functioning supply-chain is vital to the success of any public health program.

On behalf of the other members of the United States Government (USG) global health interagency partnership, USAID manages the procurement and delivery of medicines and critical commodities for the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), and the President's Malaria Initiative (PMI), as well as for USAID's programs in voluntary family planning, maternal and child health, and other health areas.

Our supply-chain activities also provide technical assistance to build capacity and expertise in partner countries to deliver, routinely and licitly, life-saving products purchased with revenues raised locally or from other donors, while also improving trust in local health institutions and services. This technical assistance is an important contributor to Administrator Green and Ambassador Bix's shared vision of moving countries along the path to self-reliance. I am here today to discuss with you the work we do in supply-chain management and the procurement of medicines and commodities; provide an update on the performance of our current contractor in this area; share our experience and lessons learned to date; and describe the path forward.

Background

For decades, USAID has been a world leader in providing critical, life-saving medicines and commodities for public health programs. The generosity of the American people has helped many millions of men, women, and children around the world avoid and recover from illness, and saved millions of lives.

The success of the U.S. Government's global health programs has depended on our investments to ensure the consistent availability of high-quality products for HIV/AIDS, malaria, voluntary family planning and reproductive health, maternal and child health, and other health programs in the countries where we work. Today, we remain as committed as ever to that mission.

USAID's internal supply-chain staff work together with clinical and scientific experts from USAID, the Office of the U.S. Global AIDS Coordinator (S/GAC) at the U.S. Department of State, and the Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services (HHS) in Washington, Atlanta, and the field to ensure that the right medicines get to the right people at the right time. The clinical staff follow the latest science and international guidelines, and work with national Ministries of Health and implementing partners to select the best medicines to treat malaria, HIV, and other health ailments. They ensure that Ministries have the proper evidence-based protocols in place, and are able to train clinical staff, to use the medicines appropriately. Our supply chain staff and the clinical teams at USAID, S/GAC and HHS/CDC work together with the U.S. Government field teams and national Ministries to develop the forecasts for each product we procure, and turn them into supply plans approved by an interagency team and then given to our contractor for negotiation, purchase and delivery. This close integration ensures that science, real-world demand, and the best clinical practice drive our procurements.

In recent decades, the scale and complexity of our investments have grown dramatically to support PEPFAR and PMI, while we continue to serve other public health programs.

For example, when President George W. Bush launched PEPFAR in 2003, the number of HIV-positive people in sub-Saharan Africa who were on ARV treatment was, at most, measured in the tens of thousands. Today through PEPFAR, the U.S. Government supports more than 13.3 million patients on ARV therapy (ART), delivered through more than 80,000 different facilities. PEPFAR has played a critical role in moving HIV/AIDS from a fatal disease to a manageable, chronic condition.

PMI has had similar growth. When President Bush started it in 2006, it began in just three countries. PMI now implements 27 programs, which span 24 countries in sub-Saharan Africa and three programs in the Greater Mekong Subregion of Southeast Asia. In partnership with national governments and malaria stakeholders, PMI's investments in the prevention, treatment, and control of malaria are benefiting over half a billion (570 million) people in Africa from the Sahel, to the Horn, to Southern Africa. Significant investments in the procurement and delivery of medicines and commodities have been a core component of PMI's strategy since the very beginning.

We work with national systems in resource-constrained environments. We face – and work to address – challenges in infrastructure and limited storage; weaknesses in management within Ministries of Health and Provincial or District health offices; the threat of corruption, theft and diversion; unreliable electricity; poor road networks that require various modes of transportation (trucks, 4x4s, motorcycles, bicycles, canoes, camels and human conveyors); human-resource challenges; and, particularly, significant barriers to reach rural, hard-to-reach communities so products are available, affordable, and accessible.

Global Health Supply-Chain - Procurement and Supply-Management

From 2005 to 2017, USAID managed our procurement and supply-chain operations under two, large, single-award Indefinite-Quantity Contracts (ICQs), DELIVER and Supply-Chain Management Systems (SCMS).

The design process for our current supply-chain architecture commenced in 2012, and sought to incorporate lessons learned from the predecessor projects, improve management efficiencies both internal to USAID and through the contract mechanisms, and continue to find cost savings in the purchase of medicines and commodities. The design team undertook a process to solicit input from a variety of sources, including across the Agency, in Washington and the field, and from interagency organizations and initiatives including S/GAC, HHS/CDC, and PMI. For example, the design team launched a 38-question survey, which generated responses from 77 USAID and HHS/CDC field staff in 29 countries. USAID also commissioned an independent expert review of our supply-chain programs compared to those of other peer institutions -- Gavi, The Vaccine Alliance; the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM); the U.S. Departments of Defense and Veterans Affairs -- and commercial supply-chains --Hewlett-Packard, Limited Brands, Pitney Bowes Canada, and Ryder Integrated Logistics, to build on existing strengths while applying state-of-the-art and commercial-sector best practices.

One of the key findings from this process was that U.S. Government country teams experienced a heavy management burden in the field to prevent or minimize duplication of two U.S. systems (multiple warehouses, two offices in one country, etc.) at the field level. The independent expert review also suggested alternative ways to organize our global supply-chain to achieve increased efficiencies. As a result of these findings, USAID made the decision to consolidate procurement and supply-chain functions across health programs through one large award, rather than two.

We recognized that a contract of this size and scope would require a consortium robust enough to implement it successfully. It would require internal systems at USAID, and for close coordination and communication between subcontractors, functional teams at the prime contractor, and U.S. Government staff in the field.

We also knew that the transition to a new contract, regardless of who would hold it, carried risks. We took best-practice measures before making the award to mitigate the risk of interruptions in supply, such as increasing inventories beyond what is normally held and ensuring sufficient overlap between the prior contracts and the new contract-- all to ensure patients' access to commodities would continue smoothly.

USAID awarded our current contract for procuring and delivering medicines and commodities and providing supply-chain technical assistance to countries in 2015. It is called the Global Health Supply-Chain - Procurement and Supply-Management Project (GHSC-PSM). GHSC-PSM began operations in January 2016 after lengthy delays during the award process because of an unsuccessful protest by one bidder to the Government Accountability Office and a lawsuit before the Federal Court of Claims, which found in favor of USAID. As a result of the built-in overlap with the predecessor contracts, GHSC-PSM¹ placed its first orders for medicines and commodities in August 2016.

The GHSC-PSM contract, awarded to Chemonics, has a total ceiling of \$9.5 billion over a performance period of up to eight years, primarily intended to support the procurement of medicines and commodities for HIV/AIDS, malaria, and voluntary family planning. Initial task orders under the contract end in November 2020.

The award of the GHSC-PSM contract followed a stringent, full and open competitive process, in accordance with the Federal Acquisition Regulations. The technical review panel, comprised of staff from USAID, S/GAC and HHS/CDC, had over 200 years of combined experience and expertise in supply-chain management, supply-chain analytics and optimization, freight and logistics, management of information technology (IT) and software-development, humanitarian supply-chains and food aid, U.S. Government contracting, HIV, malaria, tuberculosis, and voluntary family planning.

In the GHSC-PSM solicitation, USAID required offerors to provide information about their capability and value in procuring medicines and health commodities, which included instructions to "describe recent and relevant experience in order to demonstrate capability and capacity in operating a procurement program that secures best value." This also included the offeror's IT capacity and past performance relevant to the requirements of the contract.

Based on the extensive evaluation of the proposals received, USAID awarded the GHSC-PSM contract in April 2015 to a 12-member consortium led by Chemonics International, which includes world leaders in supply-chain such as IBM and Kuehne and Nagel. Chemonics proposed not only to ensure an uninterrupted supply of medicines and commodities for U.S.

Government programs in global health, but also to introduce a number of innovations and best practices that would advance our global supply-chain and strengthen our supply-chain assistance.

The GHSC-PSM contract is part of USAID's broader Global Health Supply-Chain Program that includes a suite of other contracts, grants, and cooperative agreements intended to support the U.S. Government's overall supply-chain operations and in-country technical assistance for strengthening national delivery systems. As such, we competed other, complementary awards from 2014 to 2016, including for projects to offer supply-chain technical assistance, improve the quality-assurance of drugs and supplies, improve business intelligence and analytics, and support supply-chain innovation, as well as a small-business set-aside to procure rapid diagnostic tests for HIV.

Performance Problems with GHSC-PSM

To-date, GHSC-PSM has established offices in 32 countries, and delivered or processed commodity orders to 60 countries valued at more than \$1.1 billion. Nevertheless, it is well-known that GHSC-PSM faced management challenges in the initial months of implementing the procurement and delivery component of its contract with USAID. GHSC-PSM was initially unable to buy and deliver drugs and commodities as quickly as needed, and has not yet met its contractual targets for on-time delivery (OTD¹) and on-time-in-full (OTIF²) delivery, as it reached only 31 percent for overall OTIF in Fiscal Year (FY) 2017, including a low of seven percent in the second quarter. USAID staff identified key problems with the consortium's operations, such as long lead times in processing orders, delays in the delivery of medicines and health commodities, reliance on manual systems, a lack of accountability, and team organization issues, all of which contributed to poor on-time performance.

USAID noted these issues as early as August 2016, and raised them repeatedly with project staff, orally and in writing over several months. We then escalated them to Chemonics leadership in April 2017 when the project's performance did not improve. Throughout this time, USAID staff, in Washington and the field, worked to minimize the impact of the late deliveries, including by assisting in the redistribution of commodities between facilities to prevent stock-outs. We should not have had to do so.

¹ **On-time delivery (OTD) Definition:** Percentage of line items delivered within the minimum delivery window (within -14/+7 calendar days of the agreed delivery date (ADD))

Numerator: Number of line items with an ADD during the reporting period that were delivered to the recipient on time

Denominator: Total number of line items with an ADD during the reporting period

² **On-time in full (OTIF) Definition:** Percentage of line items delivered within the minimum delivery window (within -14/+7 calendar days of the agreed delivery date (ADD)) and in the agreed-upon quantity

Numerator: Number of line items delivered to the recipient on time and in full during the reporting period

Denominator: Total number of line items delivered to the recipient during the reporting period

In response to USAID's demands for improvement, Chemonics developed and implemented an action plan to address the consortium's deficiencies. The actions included in the plan included shifting to full use of GHSC-PSM's management-information system (MIS), restructuring GHSC-PSM's global supply-chain operations, and transitioning to a new regional distribution center network. These changes have led to an improvement in Chemonics' OTD rate of (73 percent for the quarter ending in March 2018) and OTIF rate (67 percent for the same quarter).

While these improvements signal a positive trend, the consortium has more work to do to meet its contractual targets of 80 percent for both OTD and OTIF. Supplies and drugs to prevent and treat malaria remain of particular concern. OTD and OTIF for several malaria products lag behind the overall average; in response to our request, Chemonics has submitted an action plan to address these issues.

As you have heard USAID Administrator Green say, the poor contract performance we observed is not acceptable, and the Agency has taken aggressive measures to hold the contractor accountable. I can assure you the Bureau for Global Health, and the Agency as a whole, is providing a high level of oversight and scrutiny over the GHSC-PSM contract. For example, the contract is the only individual award to appear on USAID's corporate Risk Registry, and the USAID Risk-Management Council devoted a special session to it in the Fall of 2017. USAID also submitted a negative Contractor Performance Assessment Report for GHSC-PSM for the 2016-2017 year of performance, with a marginal rating, the second-lowest possible. These reports are accessible to procurement officers across the Federal Government, and are used to assess bidders' past performance during the procurement of new awards. In addition, USAID imposed a moratorium on all salary increases for staff who work on the project. The Bureau for Global Health holds weekly management meetings with Chemonics; provides weekly in-person and/or written updates to the USAID Front Office and Ambassador Birx; demands detailed quarterly reporting from the consortium, which we share with Congress and other stakeholders; commissions other reports on specific project activities; and closely monitors key performance indicators.

USAID in Washington has also worked closely with our counterparts in our missions abroad to train them to raise problems early and to oversee the performance of the contract where it matters most, in the field. We have been monitoring inventory levels in countries, and reviewing shipments, product by product, country by country, to identify the risk of stock-outs and mitigate that risk through several strategies, including coordinating with other donors to cover gaps, prioritizing shipments across countries, redistributing available stock in country, and where appropriate substituting similar products.

GHSC-PSM's Performance Improvements Since Late 2017

As a result of USAID's oversight and management actions, we have seen significant improvement in GHSC-PSM's overall, OTD and OTIF performance. Based on GHSC-PSM's quarterly report for January through March 2018:

- Chemonics increased overall OTD from 31 percent in the fourth quarter of FY 2017 to 72 percent in the first quarter of FY 2018, and maintained it at 73 percent in the most recent quarter ending in March 2018. OTD reached 82 percent for deliveries in the month of December 2017, exceeding our target of 80 percent.
- OTIF delivery also improved from 32 percent at the end of September 2017 to 67 percent for the quarter that ended in March 2018, and it is beginning to converge with OTD.
- The consortium reduced the backlog of undelivered orders by 69 percent in the quarter that ended in December 2017, and diminished it by an additional 14 percent in the most recent quarter; the backlog is now under five percent of total shipments, an industry standard.
- The volume of medicines and commodities the consortium delivered increased by 37 percent from September to December 2017, a level maintained in the second quarter of FY 2018.

While we find the consortium's overall performance improvements encouraging, they are not universal, and do not yet meet the targets specified in the contract. Malaria-specific OTD lags seriously behind overall OTD in the most recent quarter. We continue to hold GHSC-PSM accountable, and will not be satisfied until GHSC-PSM routinely meets all of its performance targets across all health elements. This includes sustaining both and OTD and OTIF delivery rate of 80 percent, quarter over quarter, which means 80 percent of deliveries arrive in the period between 14 days before and seven days after the agreed delivery date.

GHSC-PSM Is Not the End of the Story: What Happens to Drugs and Commodities Purchased by the U.S. Government When They Arrive in Country, from the Central Level to Facilities

GHSC-PSM's performance problems covered the first part of the supply-chain---from processing orders with manufacturers through delivery to a country. Yet the end-to-end supply-chain extends from manufacturing all the way to an individual rural health clinic, or even a household doorway, where patients receive their medicines and commodities. USAID is equally concerned with the second part of the supply-chain---how these commodities move from a national warehouse to patients.

GHSC-PSM has direct custody over the products the consortium procures up to the point of delivery, which is typically a central location or warehouse in the destination country. At that point, the custody of these products, and the responsibility for their in-country distribution, varies

based on the country context. A key factor in determining the level of responsibility is a country's ability to manage and account for products reliably, whether through public- or private-sector channels. For example, in certain countries, or for specialized commodities such as insecticide-treated bed nets, a USAID contractor might have custody and management responsibility for the product to the point of delivery at the facility level.

USAID provides strong monitoring of the country supply-chains we support. We continually monitor stock levels to identify and prevent shortages, help resolve resource gaps, and limit and investigate theft or diversion. In Nigeria, for example, U.S. Government monitoring included visits to over 1,000 facilities and warehouses last year. We work closely with the GFATM, including its Inspector General, to track the forecasting and movement of drugs and supplies in the countries in which we both fund grant programs. This monitoring, along with supply-chain assessments, provides for greater accountability, and provides data on the availability of stock to ensure patients have access to needed treatments for HIV, tuberculosis, and malaria.

USAID's technical assistance in this area has achieved results, as countries are moving along the journey to self-reliant supply chains. In the 1980s, when USAID first began strengthening country's supply-chains, the national systems we supported were parallel, managed a limited number of products, and operated out of colonial-era warehouses with inventory tracked through musty paper ledgers. The supply-chain managers had no ability to know what supplies were at each health facility, how much to resupply, or if there was a stock-out somewhere in the system. Through our financial and technical support, countries' national supply-chains have become more sophisticated. They are managing thousands of health commodities through networks of warehouses that use commercial facility-management systems and electronic management-information systems that provide inventory visibility throughout the supply chain, and, in some cases, outsource warehousing and distribution to the private sector. This allows them to serve more health facilities, and most important, more patients. For example, in 2003 Nigeria had fewer than 10,000 patients on ART; today, approximately one million HIV-positive Nigerians are on treatment. In South Africa, our assistance to the national supply chain, including by harnessing the capability of the private sector and improving the visibility of stock throughout the system, has improved product-availability at health facilities from 40 percent several years ago to over 86 percent now. In Zambia, a more-resource- constrained country, our technical assistance has led to a resilient national system that has maintained product-availability above 90 percent, even as the volume of commodities it manages has more than doubled.

What We Have Learned and How We Are Applying It

Some core lessons we have learned so far from our experience with the GHSC-PSM contract include the following:

- While unifying our global supply-chain across health programs might have gained some efficiency, it also increased our vulnerability, and reinforces the need for strong risk-mitigation measures in project-design, procurement, and management.
- Strong project leadership and management is necessary to integrate consortia successfully and quickly into a functional supply-chain program; we need to strengthen how we assess this during the procurement process.
- Operating a large and complex supply-chain requires a robust and adaptable management-information system that is functional **before** the placement of the first order; we need better ways to assess information systems during the procurement process.
- The measures we put in place to mitigate risks during the transition were critical in minimizing the impact of GHSC-PSM's poor performance on the people we serve; however, we can strengthen some aspects, such as increasing the amount of overlap between old and new contracts.
- Within the current structure of the Bureau for Global Health, supply-chain is integrated into each of the health offices, which ensures the critical link between clinical/scientific and supply-chain staff, but means we lack a single, overarching structure that links the different elements; this limited our ability to communicate with a single voice, and fragmented our initial response.

We have started to apply the above-mentioned lessons learned to the design of USAID's next-generation supply-chain program. Building on USAID's broader procurement-reform efforts, initiated by Administrator Green, we are identifying ways to be innovative in our design, procurement, and management of resulting award(s). We are reaching out to industry to learn how they procure, monitor, and measure the performance of their supply-chain providers. We will actively engage interagency partners and the field throughout the process. We are confident we can design a program that will apply industry best practices, be more efficient, minimize risk, and incentivize a high level of performance from the beginning. We are also exploring options to change the structure within the Bureau of Global Health to improve our coordination and oversight.

Conclusion

At USAID, we take our obligation to ensure good stewardship of taxpayer resources very seriously. We set a high standard for accountability. As Administrator Green has said, "Our foreign assistance funds are precious: they come from hard-working families all across this great country. We owe it to them to use these as efficiently and effectively as possible."

We identified performance issues with the GHSC-PSM contract early, and held Chemonics accountable, which has led to improvements in performance. We have worked diligently to mitigate the impact the poor performance had on those whom we serve.

We will not relax our oversight in ensuring that no patient is at risk. We are holding Chemonics and its partners accountable for continued improvements to reach and sustain their contractual goals of at least 80 percent OTD and OTIF.

We are assertively and purposefully applying what we have learned to ensure we do better in the design of our next supply-chain contract or contracts. We are engaging with the field, the leadership of the U.S. Government interagency, and industry experts to guarantee that our next program is innovative and limits risk, and, most important, that people receive the critical health products that prevent and treat life-threatening disease.

Thank you for the opportunity to speak before you today, and I look forward to answering your questions.

Mr. SMITH. Thank you.

First of all, let me thank both of you; your integrity is so high and your commitment so deep. I have been here long enough to know that, when something goes awry, as it does like this, that there is—coverup might be too strong of a word—but there is an effort to shift blame, never come fully forward with the facts and documentation. But you have done precisely the opposite.

I know, Ambassador Birx—I have had numerous conversations about this—and it is all about making sure. And you are so data-driven, but you are equally, if not more so, compassionate, and you want to ensure that the person who needs that ARV, or whatever the drug or the intervention might be, gets it on time, so he or she do not become sicker or even worse.

Now have there been consequences where anyone, as far as we know, has potentially lost their lives or was the stock that was there sufficiently available that it didn't get down to the very last one, and then, they are on zero? That would be my first question.

Again, I can't say enough. You have looked to fully expose, explain, explore, and now, aggressively remedy a situation that, for the victims of HIV/AIDS and other diseases over which you have jurisdiction, would be deleteriously affected, if not lead to their death. So, that would be the first question.

The second, I would ask, when USAID issued the request for proposals in January 2014, USAID convened a technical evaluation committee to evaluate bids. Was OGAC part of that or not?

And let me also ask, with regard to the Country Operational Plan, the COP process, can you explain that to the committee, how it relates to the distribution of ARVs and the effort of USAID and Chemonics to engage in health system strengthening?

If you could get to the issue of Nevirapine and explain that fully, as to what are the side effects, what are the problems associated with it, what are USAID and PEPFAR doing to move to other drugs like DTG? Maybe you could explain that and give us some good insights into that.

Let me finally ask—and I do have others, but I will go to my colleagues—when Chemonics did not complete the first phase of its IT system ARTMIS until August 2016, with the final phase not being completed until the end of June 2017, this is despite the fact that the new system was promised in the contract. So, they represented, obviously, that they had that capacity when they didn't. I am wondering why it was not caught that there was a lack of an IT system when the awarding of the bid occurred. Again, you might talk about the corrective actions that are being taken now to ensure that never happens again.

My understanding is that some of the top team, if not all of it, of Chemonics have been fired. If you could speak to the accountability side of all of this, both on Chemonics as well as on the government side? Because, obviously, accountability, holding people to account when they do something that has such a potentially catastrophic consequence—I liked what you said—late delivery has consequences. And so, it ought to have consequences, so that those who, either through incompetence or whatever, don't do it again.

Just a thought, and maybe there is nothing to do this, but I am hoping there was no revolving door involved with Chemonics get-

ting it or any of that. If you could give us some insights into the technical team that did the awarding? Was that completely above board and they just missed it or could there have been something more nefarious?

Ms. KOEK. Right. Perhaps I can start, and then, ask Ambassador Birx to fill in, particularly on the drug and some of the other issues.

And thank you very much, Chairman Smith, for your questions and, again, for your very close attention to this hugely important issue. I really, really do appreciate that.

So, your first question regarding whether there have been instances of people not having the drug or losing their lives, this is an issue that is of great concern. As I mentioned, we knew there would be disruption, regardless of who won the contract. So, we took steps, as I mentioned, to build in buffer stock and to make sure we had additional overlap. This is also something we have been looking at very, very closely and working with our field staff and asking them to work with their country counterparts to monitor and make sure that doesn't happen.

We are aware of two cases where delays in deliveries did have programmatic impact. One was with a bed net campaign in Nigeria where the nets were delayed in arrival. So, it delayed the start of the bed net campaign for some weeks, as I understand it. And then, also, in Ukraine, where the delays of the shipment of ARVs did delay onset of treatment by a couple of weeks for some patients. And those are the two instances that we are aware of.

It is something we continue to investigate and ask our field staff to regularly let us know of any issues. Stockouts do happen in the countries we work, right, and that is part of where the technical assistance that we do tries to make sure that the country systems are working to manage supplies, make sure that that last-mile facility does have the medicines they need to deliver. So, that is something we constantly look at. But those are the two instances.

With regard to the technical evaluation panel—and I believe and I hope this is something we have shared, but I can certainly share it again—the panel did include a representative from the Office of the Global AIDS Coordinator. It was something that was set up some years ago. As you said, it was a long, very long, long process. But it also included across-the-board expertise not only in supply chain, but people with HIV experience and maternal and child health and family planning and malaria experience. We really tried to make sure that the panel reflected the full range of expertise, as well as on IT systems and on logistics systems, and everything that we were asking for in the solicitation. I was not part of that panel. So, I can't speak to any further details. But we can certainly share with you additional information on that.

On that, let me just jump to one of your later questions. We took extraordinarily—we always take very careful precautions to make sure that the procurement and the review of those proposals is done according to the rules, according to the Federal Acquisition Regulations, and is tightly controlled. With this one, because it was so large and so competitive, we made sure that there were no issues whatsoever with the process. It was very, very tightly controlled, tight oversight by USAID. The panel was completely se-

questered for the many months. No one was aware of who was on the panel because that is part of the rules; you are not supposed to know who is sitting on the panel. But they took very, very careful steps to make sure there was full protection and no conflict of interest with the members of the panel and the decisions that were made. And that was also part of the overall review process, both within USAID——

Mr. SMITH. Just on that point, if I could? The IT assessment, who did that?

Ms. KOEK. So, as I understand it, there was a member on the panel who was an expert on IT systems, as I understand, or the expertise existed on the panel. What we asked for in the RFP was to show us what your approach to putting in an IT system. One of the criteria—it was not necessarily the first criteria, but it was among those criteria—what the proposal was, Chemonics did have components of that system in place already. What hadn't happened yet was the knitting all those pieces together, and that needed to happen once the contract was awarded, as they can make sure it was being responsive to the procurement and supply delivery, which was what the system was meant to do.

So, the startup of that system was a few months late in starting, and that was one of the issues we raised with Chemonics in April 2017. It is now up and running, and we continue to adapt it, which was one of the other things we asked for, is a system that could be flexible and adaptive to whatever we needed it to do or whatever the system needed it to do. And that is certainly what has been underway.

The proposal or the RFP—and we can share those criteria with you, if you would like; I don't have them all in front of me at the moment—did ask to propose their approach to putting the system in place. It was won on that basis, that Chemonics proposal was reviewed.

Let me talk briefly about systems strengthening. I think Ambassador Birx mentioned this. They are trying to build logistics and product delivery systems in the country where work has been a critical function of our work in supply chain since the very, very beginning days of our procurement/supply chain.

Typically, it has been about, you know, it is a relatively smaller portion of the overall money we put into procurement and supply chains. It is roughly about 15 percent of the total funding. It has had impact. I mean, we work through country systems, and our intent is to build the capacity of the systems within the country we work to procure and deliver supplies themselves. The PSM project's role is to bring commodities to the central warehouse. And then, what we want is the country system to take it from that warehouse to make sure it gets to all the facilities and that there are not stockouts. So, the technical assistance and the work we do is meant to improve those systems.

There has been tremendous progress in that, and it is country by country. There is wide variability from one country to another of this year's. A good example is Zambia, where we started working in Zambia in the late 1980s, where it was a very poor system, you know, product shipped out whether or not it was needed, or paying not a whole lot of attention to whether there were stockouts. But,

over the years, have helped the Zambians build a system that has a network of warehouses, that is using technology to make sure product is getting where it needs to go and is a high-functioning system. So, it does make changes, and this is a system that started with just a few products, but, then, was able to take on all of the product of PEPFAR as well as PMI over the years. So, there certainly is progress there.

Let me maybe turn to Ambassador Birx for the questions on Nevirapine and TLD, and I can add on the supply chain after she answers that.

Ambassador BIRX. Great. Thank you.

So, just a couple of comments. I was not at OGAC when the technical review committee was meeting. I know CDC. I was at CDC at the time. And so, we had awareness that USAID was letting out an RFP for a combined agreement, and that was the depth of our awareness.

When I came to OGAC, I found out about the award through the public system when it was announced publicly. But I think that there were procurement concerns, and I guess other concerns. So, we were not aware of the award until it was announced publicly.

That said, I think this whole issue of supply chain—and thank you for the hearing because it has really asked us to step back, to really say, like Congresswoman Bass said, why 15 years in are we talking about glitches in the system, not just glitches at the central warehouse, where Chemonics is responsible? And the perception that the commodities are not there when they are supposed to be sends a ripple effect down through the system. People will adjust, so that they don't have stockouts. They will adjust to giving clients a 2-weeks' supply. They will adjust to giving them a 1-month supply.

There is good communication between the system. And so, whenever there is a concern that something will be late, people adjust, so that clients don't actually miss out on their medication. And so, a lot of those adjustments have been happening.

We will find out that clients that are supposed to get a 3-months' supply are only getting a 2-month supply. That requires them to come back, then, multiple times. Those are the issues that often emerge in the transmission from the warehouse to the site.

So, we really need to look at these \$3 billion that we have invested just since 2009 and say, are we investing correctly with technical assistance to really create a system that has the resilience to meet the demands of the future? Because with that level of investment over this amount of time, we would have a different expectation. When you look at the laboratory systems and how far they have come, when you look at task shifting within the health cadres and how we have trained nurses to do what doctors have done and community health workers to do what nurses have done, when we see all the progress we have made in other areas to allow 14 million people to be on treatment, when you talk to the Global Fund, when you talk to the field, the one comment that continues to come up is the integrity of the supply chain. So, there is an issue there that persists, despite a significant investment.

And so, we are looking at all aspects of this. Maybe our conceptual framework about how to support a supply chain may be old

school, and maybe we have to look at this differently. We are working with USAID on each of those issues.

At the same time, we have been trying to streamline what we ask for. So, as we move to viral load, to save money, we have taken out CD4 counts because they are no longer needed. So, that simplifies the supply chain of who needs what when. We are also trying to simplify to a single first-line and a common second-line, so that countries can move supplies, as described, between warehouses and between sites, because the clients are on the same thing.

I think, most importantly, if you go to pepfar.gov today, you will see our results down to the site level and the targets at the site level, as you described about the country operational plans. And so, any supplier should be able to look at that and know precisely what the needs are at that site over the next 12 months to create forecasting, procurement, and delivery. And so, this is now publicly available, open to everyone, including the people on the ground, so that they can assure that they have access to the same data that we have.

I think the Nevirapine issue is a real illustration how Administrator Green and Chief of Staff Bill Steiger and Irene have worked with this. When we found out just 3 months ago that we were still utilizing Nevirapine-based products, what does that mean? That means that was a product that was created in the mid-2000s. Often, children were put on this combination, Nevirapine-based product.

The interesting piece of it, we were asking the question, why aren't young adults virally suppressed? We have been putting these surveys in the field at the community level. We have found, whereas adults over 25 were about 90 percent virally suppressed, if you were between 15 and 24, your viral suppression was around 60 to 70 percent. We couldn't understand it.

If some of those clients had been on Nevirapine since childhood and kept on a Nevirapine-based product, we know they are more likely to have drug resistance. And so, the team at USAID and the team at OGAC have been working very hard to actually cancel orders. Now you would say, how does this happen? Well, countries request, ministries of health request, partners are requesting these drugs, but this awareness has really increased our awareness and allowed us to find this legacy ordering. They have already been able to cancel orders with no cost, so that we can move to a more effective regimen for adolescents and young adults.

I think we should be very proud that, out of this hearing and out of the COP development process, and this change to this new drug that you mentioned, the TLD drug that is based on DTG, dolutegravir, that has really brought out all of the issues about what drugs we are utilizing. And the Global Fund very much relies on the U.S. Government to really, because we have the boots on the ground, to work with governments and communities to ensure that the best drugs are being ordered.

And so now, we have really in the last just 3 months, what often would have taken us a year to fix, we are now fixing it in a matter of weeks. I think this level of oversight translates down to our more constant awareness of what is occurring, and we have put in

a lot of checks and balances at the State Department to ensure that we are aware of all the aspects of the functioning of the supply chain.

But we still have substantial work to do between the warehouse and the clinic. Because we have spent, if you remember, you all have done so much work with us and FDA to ensure that a new drug, a branded drug that is highly effective in the United States or Europe is immediately worked on licensure agreements to take them to generics and to get waived through their expedited FDA approval process. That has allowed us to move the best drugs to the countries immediately, so that they can take advantage of all of our scientific advances.

That movement and that rapidness has allowed us to really look at our procurement processes and really find where we are still having these gaps. And then, we really need at each one of these gaps, as described, to have a solution where we quarterly monitor our improvement. We want to take the same thing that we have taken to the clinic on ensuring that clients are doing well by looking at their viral load suppression, to have that same level of data out of the supply chain, so we can really monitor stocks as they move to the clinics where they are needed.

That will allow us to decrease expiries and, also, to ensure that there is agreement between what partners report on people on treatment and what drugs are being utilized at the site. So, it is a double-check to ensure that there is validity and validation of all aspects of the program.

Mr. SMITH. Ranking Member Bass?

Ms. BASS. Thank you very much. Thank you for your testimony.

So, I still would like to understand the process. Chemonics, I was looking on their Web site while you were speaking. There is not a ton of information there. It is not clear to me if it is an NGO or a for-profit, who runs it, who owns it. None of that is clear. Maybe you have the answers.

And then, in the contracting process, you give a contract out. It sounded like, Dr. Birx, it sounded like USAID does an awful lot of the work, from what you were describing. And so, I thought that is what the contractor did, a lot of what you were describing. How do these contracts work? Is it cost reimbursement? They deliver; you pay? This is a \$9 billion contract, right? It was \$3 billion since 1997. That is a heck of a lot of money.

Ms. KOEK. Thank you very much, Representative Bass.

So, the \$9 billion is a ceiling for over the 8 years of the contract. We haven't given that money to Chemonics as yet, but it is a ceiling for a contract.

I will have to confirm of whether it is a—what is the type of contract?—whether it is a for-profit or—

Ms. BASS. For-profit or not-for-profit.

Ms. KOEK. I believe Chemonics is a for-profit, but I don't know. We don't award contracts based on what the institution is per se. We award contracts based on how their proposals meet the criteria, which does, indeed, include past performance as an important component of that.

Ms. BASS. Well, it is also important if it is a for-profit. Because if it is a for-profit, they are going to look, obviously—

Ms. KOEK. Yes.

Ms. BASS [continuing]. At what their bottom line is. And so, how do they make money?

Ms. KOEK. Absolutely.

Ms. BASS. How do they earn a profit off of taxpayer dollars delivering services that they don't provide?

Ms. KOEK. Well, the issues with Chemonics' performance was about the on-time delivery. They did, indeed, deliver the product. They just did it late and not on time, and not on time with a fairly narrow window.

Ms. BASS. And so, what is late?

Ms. KOEK. Late is, the way we describe or define on-time delivery is within a 21-day period. So, 2 weeks before a date and 1 week after is when we expect the product to be delivered. I would note that that is a narrower window than the predecessor contracts had, which was much longer. So, we are holding them to a higher level of accountability than previously.

Ms. BASS. Some medications—

Ms. KOEK. I'm sorry?

Ms. BASS [continuing]. It is difficult to be interrupted in your therapy by late—

Ms. KOEK. Well, when you do a procurement, when countries do procurement orders, you plan for when the drugs need to be there. So, the date for procurement shouldn't be the day you are about to stock out, right? You need to have enough timing and plan, as Ambassador Birx was talking about, through the system to make sure product can get through the system to where it is. So, this is product going to a central warehouse.

Ms. BASS. So, when did you find out—and I don't mean you personally, of course—that they were having a problem?

Ms. KOEK. Our staff identified the problem fairly early on. It was probably in August 2016 that they identified there were some issues.

Ms. BASS. And how long had the problem been going on?

Ms. KOEK. Well, that was at about the time that Chemonics started. That was when Chemonics first started doing the purchase and did their first purchase and started the delivery process. We had had an overlap between the two contracts for a number of months, and it was very early on that our staff identified that problem. And they raised it and there were some attempts to fix it, and they continued to escalate the issue all the way through until we sent a formal letter to the head of Chemonics in April 2017.

Ms. BASS. So, your staff identified it?

Ms. KOEK. That is correct.

Ms. BASS. As opposed to the contractor saying, "I'm having problems finishing my contract."?

Ms. KOEK. There was a lot of discussion back and forth. I can't speak to exactly what those discussions were. I believe the contractor did identify that there were also issues and did try to address it. I would have to come back to you on exactly what those discussions were and what those issues were.

Ms. BASS. And so, what penalty did they receive for being late?

Ms. KOEK. There were a number of corrective actions. As per a question Chairman Smith asked, they implemented an action plan

and they replaced all of their, most of their senior staff. So, many of those senior staff were removed and replaced by others.

Ms. BASS. And that is a correction plan. My question is—

Ms. KOEK. It was part of a correction plan. In addition, as part of our process, we do ratings of the contractors we have. They received a negative rating, which affects any other business they are likely to get from the Federal Government, because you look at those as part of your past performance. So, that would certainly affect—

Ms. BASS. But their contract is not stopped?

Ms. KOEK. Their contract is not stopped, right, because they did continue to deliver the product. They were just not meeting the on-time delivery metric.

Ms. BASS. And so, when they are late, is there a financial penalty that they pay for being late?

Ms. KOEK. There is not a financial penalty that I am aware of in the contract, but I would have to confirm that. But they did deliver the product. They did purchase and deliver the product. They did not meet the on-time delivery metric.

We also put a moratorium on any raises on the contract staff and refused to allow them to make any raises. And as part of our corrective action plan that they proposed, and we accepted and they completed, there were a number of other things. They accelerated the MIS system that we talked about a few minutes ago, and they made some changes and simplified and straightened out their systems and their management system.

Ms. BASS. And I believe that you said that now they are about at 60 percent, did you say?

Ms. KOEK. They are overall 73 percent on-time delivery, yes.

Ms. BASS. So, 20-plus-percent is still late?

Ms. KOEK. Well, the target is 80 percent.

Ms. BASS. Oh, the target is not 100 percent?

Ms. KOEK. No, it is not 100 percent because there are always things, and I think industry standards are much lower than that. But our target is 80 percent on-time delivery within that 21-day window.

Ms. BASS. I ask you these questions because I am just really trying to understand what processes we use. And I think, like my colleague Mr. Garrett was mentioning, this is a tremendous amount of money. In the normal course of doing business, I mean, it is one thing to be late if you are delivering shoes; it is another thing to be late if you are delivering lifesaving medication where you can't have interruptions. I know you said that the countries account for—it is not like they run out completely, but I don't know that. And I would ask if you do, because if you are 21 days late, some of the countries have 30-, 40-, 50-day supplies? I would just question that in some of the places.

Ms. KOEK. No, and it is something we are very concerned about and constantly monitor to make sure there are not issues with stockouts because that is the most critical piece here, is making sure patients have access to the drugs when they need them, whether that be for malaria, for HIV/AIDS, et cetera, that there is no interruption in treatment. So, our teams on the ground, which is a combination both of the contractor teams as well as our U.S.

Government staff, work very closely to make sure that orders are put in place in a time to make sure there is no interruption. So, those are all part of a fairly complex process to make sure you are doing the orders on time and that, when the orders do come in, they meet that and you can send the supplies down, all the way down to the facilities, because they have to go through the systems in-country.

Ms. BASS. So, there was a challenge to this contract?

Ms. KOEK. That is correct.

Ms. BASS. And why was there a challenge? I mean, I read that there was one. It went to court and it didn't hold, but I didn't understand why there was a challenge.

Ms. KOEK. So, it is not uncommon when there is another bidder to challenge the decision. The losing bidder would do so. So, the losing bidder did challenge it through the General Accountability Office, which reviewed the challenge and reviewed the challenge against all of the documentation that we made about our decision, and concurred with our decision and found in favor of USAID. Then, they raised a claim with the Court of Federal Claims, who also found in favor of USAID and dismissed the challenge.

Ms. BASS. So, a slightly different subject, recently, there have been tariffs that were imposed on products from China, and there is 1300 products that are on that list. Some of those products are rapid diagnostic tests for malaria, vaccines, and other critical compounds. Does that impact any of what—you know, since part of this contract was malaria drugs as well, correct?

Ms. KOEK. Yes, malaria drugs are certainly part of the contract, yes. I don't have any information on that. I would have to get back to you. We could investigate and get back to you on that question.

Ms. BASS. Okay. One of the big things I really would like for you to get back to me on is the question as to whether or not this is a for-profit company, whether the company is still paid by being late, which is an interesting thing, I think. In a lot of businesses you don't just continue getting paid if you don't fulfill your objectives, even if you are—the product eventually gets there; it is just late. It doesn't sound like there is any financial penalty at all. And how do companies that are for-profit make a profit in this way? Do you know what I mean? Those are taxpayer dollars. So, if I sell less or cheaper or inferior products, I increase my bottom line. How do you work with for-profit companies in this space?

Ms. KOEK. I would be happy to share some information about that, both about Chemonics and the structure of the contract and those issues. We will share that with you after. I don't have that information with me now, but I would certainly be happy to do so.

Ms. BASS. And just in closing, Mr. Chair, again, I raise these questions because I think that they are questions that are bigger than just this contract. It is about how USAID does business, period. When my colleague over there is concerned about waste, it depends on how you look at waste. And so, anyway, I ask these questions because I just question how we do business sometimes.

Thank you.

Mr. SMITH. Mr. Garrett?

Mr. GARRETT. Thank you, Mr. Chairman.

And thanks to Ranking Member Bass. I think there is a little synergy here.

I want to preface my questions and comments with this caveat, and that is that I am not targeting you ladies, although it may sound like it. But there is some frustration here.

It is over a \$9 billion contract. I would just like to break that down for folks in my district. That is 9 million times \$1,000. And the waste is mind-numbing.

Ms. KOEK, you have indicated that, in August 2016, your staff identified the problem, is that correct?

Ms. KOEK. Yes, sir, or started to identify, yes.

Mr. GARRETT. Okay, but the on-time, in-full delivery in August 2016, based on the data that we have received, is probably somewhere in the 50 percent range, and that was near the beginning of this contract, correct?

Ms. KOEK. In August 2016, our staff started to identify some issues, because a lot of these issues were about the management and how the contractor was working to manage the processes.

Mr. GARRETT. Is it correct, though, that the on-time and full delivery around August 2016, based on the data you have provided to this committee today, would have been in the ballpark of 50 percent plus or minus 10?

Ms. KOEK. I don't—

Mr. GARRETT. But that sounds about right, based on the data that is in front of me. Okay. And so, it is also correct, then, that the trend of on-time and full delivery continued downward from that point, let's say roughly 50 percent, to a low for an entire quarter of a year of 7 percent in the January-through-March quarter of 2017, is that correct?

Ms. KOEK. That is correct.

Mr. GARRETT. Okay. So, you identified the problem in August, and then, January through March, the problem had exponentially increased? Accurately depicted?

So, then, you indicated that you sent a letter to Chemonics in April 2017. Okay. With all due respect—and again, you are not the target here—but what took us so long?

Ms. KOEK. Thank you, sir. Let me describe a little bit of the process. So, in August 2016, that was when Chemonics first placed their first order. At the time, our staff identified that there were likely to be some issues. They hadn't yet made those deliveries at that time. Because there is a long lead time for many of the products we do, you don't necessarily send an order and have the order delivered the following week. There is typically several months in between the lead time between the order and the delivery.

Mr. GARRETT. But the contract initiated in July 2016, and we identified weaknesses and the delay in on-time and full delivery in August 2016, a month later, which continued precipitously downward through the first quarter of 2017. And then, in April, we sent a letter. Is that accurate? Again, I'm not after you. I want to understand what happened.

Ms. KOEK. No, I appreciate that, sir. So, Chemonics began the ordering/delivery in August 2016.

Mr. GARRETT. And we immediately identified a shortcoming in Chemonics' performance as related to that 80 percent goal of on-time and full delivery? Immediately?

Ms. KOEK. We identified there were some issues within their management system.

Mr. GARRETT. I'm not trying to be short with you.

Ms. KOEK. No, sir.

Mr. GARRETT. But this is sort of yes-or-no stuff.

Ms. KOEK. Yes. We identified issues with it. They had not yet delivered any product at that moment in time. So, we continued to escalate the issues within Chemonics. Our staff identified the problem. They did some reorganization. It didn't fix the problems. Indeed, as you noted, the lowest point was 7 percent in that first quarter of 2017.

Mr. GARRETT. And that was for an entire quarter. Again, I am not trying to interrupt you, but it wasn't 7 percent for a day; it was 7 percent over a 3-month period.

Ms. KOEK. That is correct. That is correct. Exactly, our reaction was similar to yours; we were very, very concerned. So, continued to escalate the problem.

Mr. GARRETT. So, help me help you here, because I think we want to get the same thing. And let me just digress for a moment. So many times in government—and I have worked in local government, I have worked in state government, I have worked in Federal Government—and you guys, to your credit, at one point I heard something to this end a little bit. It is, well, it is a funding problem. Well, if you are at 7 percent, then I suppose you could increase your expenditures by 14.2-fold and get to the aspirational 100 percent.

But when you are \$21 trillion in debt, right—and I support this program. Earlier, Dr. Birx, you suggested that PEPFAR works, and I would submit that we know PEPFAR works. There are 14 million living, breathing, walking pieces of evidence that PEPFAR works; 2.2 million children born without HIV that attest to the fact that PEPFAR works. But how do I tell my colleagues that this is a good expenditure when we are at 7 percent for a quarter?

I am just getting warmed up though. So, I am here to support the program, but how can I support a program that throws proverbially bad money after good?

All right. So, we identified, within a month of beginning the contract with Chemonics, a shortcoming in the OTIF, the on-time and full delivery. Then, in April, we sent a letter. Okay. Now we are going to move forward.

Chemonics' on-time and full delivery was 31 percent, October to December 2016; dropped to 7 percent January to March 2016. We have seen an upward increase. You have addressed this problem. I am satisfied with your comments to that end.

Congresswoman Bass asked this question, and I am going to be redundant here. I think I know the answer. Chemonics has been paid. One party to this contract has upheld their side of the bargain, am I correct? That would be us paying them the portion of the \$9-some-odd billion in the contract. Chemonics has been paid, correct?

Ms. KOEK. Yes, sir. They haven't been paid 9.—

Mr. GARRETT. No, I understand, because the contract is over a number of years.

Ms. KOEK. Yes.

Mr. GARRETT. But they have been paid. And was their pay docked? Was it prorated based on their failure to achieve on-time and full delivery?

Ms. KOEK. I would have to get back to you on that. The bulk of the cost of this contract is, indeed, the commodities themselves, so the purchase of the commodities. That is where the bulk of the—

Mr. GARRETT. But, to Congresswoman Bass' point, and I wish she were still here, there is some overage because they have to make some money. I have no problem with dealing with for-profit entities whatsoever, but they shouldn't be bilking the taxpayers, right? They should make cost-plus-\$1, so that they can support the individuals who make the organization run.

And the reason we work with for-profit entities is because there is incentivization of efficiencies. And we should choose, because I am going to get to the RFP process in a second, the people who can give us what we need at the best cost, right? That is what competition and free markets are about.

But I would wager—and I do want to know. I have staff here. A lot of times in these committees I watch my peers say, "Could you get back to me on 'X'?" If you don't get back to us on this—and again, not a threat; I love you guys—if you don't get back to us on this, we are going to get back to you.

Because I want to know. Can we see a list? You said individuals from Chemonics have been fired. I would love to have a list by full name of the individuals at Chemonics who were fired as a result of the failure to meet the requirements of this contract by Chemonics. Can you please produce for us who got canned and when directly related to this failure? And I know you can't today. If you can, I would be shocked and impressed. Can I get one of those? Can our office get one of those?

Ms. KOEK. We would certainly be happy to share the names of the people who were removed from the project and moved off the project.

Mr. GARRETT. I don't care who was moved off the project. I want to know who got shown the door. I mean, what happens all too often is you waste government money and you get moved to another department, right? So, if you can get that for us, I would be very grateful.

And I would like to make that part of the record, per the chairman's suggestion.

In the filing of the RFP, has there been any OIG review of USAID and PEPFAR decisionmaking and decisionmakers as it relates to preexisting relationships with individuals at Chemonics? Any OIG review of the process of awarding of this contract, this \$9-plus-billion contract?

Ms. KOEK. There is currently an OIG review on the performance of the contract, I believe. I can share with you exactly what the questions are. There is also another OIG review that is looking at what happens at country level and how product is protected, and how do we manage the risks of theft at country level.

Mr. GARRETT. Well, I understand the country-level theft thing for absolute. I mean, we want to help the nations, for example, of Afghanistan, and we send a dollar over there, and 50 cents trickles down and 50 cents is pilfered. We still have a duty, I think, to try to help, but we need to reduce and minimize that pilfering.

Has anyone ever reviewed whether there were any preexisting relationships between staff and leadership at Chemonics and the U.S. Government staff, USAID and PEPFAR, prior to the awarding of this contract, whether there was any nepotism, any sort of pre-existing friendships, et cetera?

Ms. KOEK. So, there has not been an OIG review. However, at the beginning, when one signs on to be part of this procurement panel to review the proposals, et cetera, you are required to sign a conflict-of-interest statement that shows that you have no conflict of interest for any of the proposed bidders or anyone listed on the proposals. And that is part of what is, indeed, reviewed as part of the oversight of that process.

Mr. GARRETT. Can you provide to us a list of the decisionmakers who would have been responsible for the RFP process as it related to the \$9-plus billion awarded to Chemonics by name? Can we know who those people, who those decisionmakers were?

Ms. KOEK. We have certainly shared the information about the membership on the committees with Chairman Royce. We would be happy to share that again with you.

Mr. GARRETT. Thank you very much.

And this is really the \$64,000 question, if you will pardon me using such paltry small sums. Do we have any idea the impact in human lives of a sub-500—and I just do that averaging it over the length of this contract so far—of a sub-500 OTF, on-time and full delivery? Do we know how many people aren't alive? I understand that they try to give you 3 months out, but when you are at 7 percent, 3 months out mathematically, there are people who are going without this treatment. Do we have any quantifiable sort of data on human lives?

Ms. KOEK. Well, as I mentioned earlier, this is something we have been paying very close attention to and looking for and trying to identify where there may have been issues as a result of the late deliveries.

Mr. GARRETT. Completely, with all due respect, the answer, then, would be no?

Ms. KOEK. We don't have that data. As I mentioned, there are two places where there was programmatic impact as a result of the late deliveries.

Mr. GARRETT. So, I am going to walk this dog two more steps farther down the trail here. So, we don't know the loss of life. Do we have any way of knowing the number of people who might have been infected by virtue of the failures in delivery?

Ms. KOEK. No, sir.

Mr. GARRETT. And do we have any way of knowing the number of children who might—because PEPFAR has done good work—do we have any way of knowing the number of children who might have been born infected with HIV by virtue of the failure of Chemonics to uphold their end, which would allow for on-time delivery?

Ms. KOEK. As I mentioned, there were these two instances, in Ukraine and in Nigeria, where people were delayed putting on treatment in Ukraine and a bed net campaign was delayed in Nigeria. And that's the only programmatic instance we know of. We have continued to look to see where there have been other programmatic issues or where there may be that kind of impact that you are talking about. That is exactly what we want to do everything we can to avoid, and work very closely with our contacts, our partners on the ground to make sure there were not the stockouts, there was not the kind of impact that you are describing.

Mr. GARRETT. So, in closing, and at the risk of redundancy, I would request, humbly before the committee and on the record, that you produce for our office a list of individuals from Chemonics who were released—that is, terminated, not moved from one department to another—as a result of the failure of Chemonics to uphold their contract with the citizens and taxpayers of the United States and the citizens of the world to whom we made a commitment. I would like a list of who got fired. I would also like a list of decisionmakers as it relates to the awarding of the RFP inside of the apparatus wherein that decision was made as soon as possible. I am very curious as to any quantifiable numbers on the loss of life, the infection rate, and the number of children who might have been born HIV-positive as a result of these failures. And I would also like to see, in sort of a simplified version, the plan of action moving forward as it relates to how we avoid this in the future, something, even a one-pager. What are we doing with specificity?

And I want to sincerely apologize to you because I am not after you, but I am after this. This isn't right. We have a good program that is working that helps America save lives and save American lives down the road, as I see it, by virtue of building goodwill in the global community. What it looks like here is that the taxpayers have been defrauded.

Ms. KOEK. If I could just mention a couple of things, and certainly about the path forward, but also just to be clearer. They did, indeed, buy and deliver the commodities. There was not fraud.

Mr. GARRETT. I totally understand that. You are absolutely correct.

Ms. KOEK. Right.

Mr. GARRETT. It was never timely ever. It is still not timely by our goals at 80 percent. Let's say that the profit margin is 10 percent. Ten percent of \$9-X billion is still a thousand thousand thousand dollars over the course of the entire contract. I know it is not that yet. It may only be 100 million. Where I live that is a lot of money.

Tragically, we could do this all day with a million different programs. But if somebody in this building—thanks to Congresswoman Bass, thanks to Chairman Smith—doesn't start shining lights on this, it is a death by a thousand cuts.

Again, it becomes hard for me as a fiscal sort of watchdog to justify to my peers why foreign aid matters, and, by gosh, it does. So, we need to do this right, or else we are going to stop doing it. And then, that is dead human beings.

Again, I am not trying to lecture you. You guys are doing good work.

Please, please get us this data. I think there are some next steps that can be taken without cameras rolling.

Again, thank you for, 1984, a lifetime of service. Thank you as well, Dr. Birx. Again, please in no way, shape, or form mistake my tone as attacking you. You are defending something that is entirely defensible, entirely good, but we have got to get it right. We have a duty to get it right.

Thank you, Mr. Chairman.

Mr. SMITH. Thank you. Thank you, Mr. Garrett, and I want to thank you for your leadership.

You know, Mr. Garrett is a former prosecutor, and he does ask very incisive questions. I do appreciate that. He is a real asset to this committee.

Let me just ask some final questions. And if Mr. Garrett has any further questions, I would be happy to yield to him again.

Before Chemonics was awarded the contract in 2014, were there reports from the field regarding past poor performance, such as from Ethiopia?

Next, if you could, in the continuum of what would be a high-performing supply chain, where were the glitches on this one? We know it is delivery. I believe that UPS was one of the losers in terms of the request to be part of that consortium. Who actually does the delivery? Is that where the glitch was? Where was the glitch? I know the IT problem is very real, was. Hopefully, it is "was."

Let me ask, thirdly, do you have the authority to penalize a non-performing entity? And if not, if you could get back to us as to whether or not you think that would be advisable?

I have many instances in my district over the years where we have had poor performance on the part of a low-bid contractor, or any bid contractor. One of them was years ago with an outpatient clinic that I worked for 10 years to get for the Veteran's Affairs Administration. The low bid got it rather than best value, which I thought was unfortunate. But, frankly, they were a year late, and then, a year and a half late. An outpatient clinic means veterans don't get the care they need. So, I petitioned the VA to use their authority to impose a daily fine in order to get that job done. All of a sudden, there were workers all over that site and they got it done very quickly, but it wasn't until sort of Damocles, a serious threat—and that wasn't just offered as a possibility; it was imposed—that they got the job done. Would that authority be helpful to you?

How many other Chemonics contracts are there? And can you perhaps provide us some insight as to the percentage vis-a-vis others in that same realm? Has or will Chemonics' deficiency in delivery—on-time delivery—affect the future of any awards? When a team looks at a new project, and Chemonics comes forward, short of disbarment—you know, past is prologue sometimes, too often—will that become a factor in whether or not they get a new award?

Ms. KOEK. Great. Thank you very much, sir.

I don't have the information, past performance information in front of me. I would be happy to share that and take a look at that information. We will get that to you.

In terms of the glitches, the glitches were things that we had identified, and certainly was in what was proposed in terms of the management structures were not working as we expected. So, among the things we asked them to address, and they proposed to address as part of the action plan, included accelerating the MIS system, as we have discussed; restructuring the supply chain operations. And this is also removing staff off, as we have also discussed. Changing the project leadership and transitioning to a regional warehouse distribution system, and a number of other things. So, there were glitches in things that were not moving through the system as they needed to, and the information and the requests were not moving through the system as they needed to and being processed in a timely manner.

There were also issues with making the estimates of when something would be delivered, and that was also a piece that they did improve and make sure that the estimates that they were making really did reflect what was a much more likely outcome, which is hugely important.

Penalizing poor performance, we would be happy to share this there and how the contract is structured in response to—

Mr. SMITH. Again, if that authority does not exist, it is something we would, with your concurrence and working in a way that is likely to lead to the best outcome. It does work in other government agencies. I know it for a fact. It might work here.

Ms. KOEK. Yes. Well, I will have to get back to you about that. That is not information I have. And I also will have to get back to you on how many contracts Chemonics has. I don't know. I will say they have been very responsive to the action plan and have improved their system, which we are encouraged by. But, as we have noted, they are not where they need to be as yet.

The poor performance, as I mentioned earlier, in this, you know, the database. For every contract, you have give reports on a regular basis about what is the performance of the contract. It is something that everybody across the Federal Government uses when you are choosing based on past performance. So, it is an extraordinarily influential piece of information.

As I mentioned, Chemonics did get a minimal rating early on, and we will continue to have that documented as they—

Mr. SMITH. Now has that affected any contract since this all came about?

Ms. KOEK. There is no way I could answer that because I don't know what decisions other have made.

Mr. SMITH. But in terms of were there contracts to Chemonics after all of this became known?

Ms. KOEK. I don't have that information, either.

Mr. SMITH. Could you provide that? It will be interesting and insightful to know whether or not that minimal rating was taken into consideration or just bypassed.

Ms. KOEK. I mean, it is certainly something, as we looked at, the past performance, that would be something that would absolutely

have an impact in your ranking or your assessment of a bidder, as to whether they have had that kind of a rating.

Mr. SMITH. Again, in another agency—this was the Department of Defense—I had a big fight with a contractor that was providing security services at Earle, which is a naval base in my district. It is an ammunition depot. We discovered that the poorly performing contractor for base security, not the Navy, but the others, was just doing a very poor job. And I knew it when a whistleblower came to me and said, “I kept noticing one of the people they had hired, and I kept saying I know you. I couldn’t figure out where.” He was a former Jersey City police officer. “And then, in the middle-of-the-night kind of thing, I said, I arrested him once.”

Here he is, had not been vetted the way he should have been. I brought it to the IG; I brought it to the Navy. It took, basically, seemingly forever to get that fixed. This is base security. And then, they finally, only because I just kept pushing, decided—they didn’t disbar—but they made it very strong because this was truly they didn’t do the training that was required.

So, I think agencywide, governmentwide, we do have a problem everywhere. I have had a lot of experience in my own district where this has happened.

Again, if Chemonics got a number of contracts after this, my hope would be that this would have been taken into very serious consideration when juxtaposed with another person or group that was trying to get that contract, because failure to deliver on time is very important.

If you could get back on the authorities and all of those?

Ms. KOEK. I would be happy to get back to you on some of those other questions, absolutely.

Mr. SMITH. Thank you.

Madam Ambassador?

Ambassador BIRX. Just a quick comment. At the same time with the Chemonics issue—and I heard about the industrial standard of 80 percent—at the same time, we are asking countries to have 90 percent of their population aware of their HIV status. So, the world has changed to a much more rigorous, much more accountable, much more transparency in our frame. I think all of our systems need to get to that same place. If we can expect that 90 percent of children know their status, 90 percent of teenagers, and 90 percent of adults, we need to expect that we are all moving with that same level.

Is it hard to work for PEPFAR? I think it is very hard to work for PEPFAR. The demands, the fact that it is absolutely lifesaving, and it is a difference between a mother being diagnosed and put on treatment that day or not. And I think, yes, our standards are probably the highest in the world because of the issues of us trying to stop an epidemic.

So, I think part of this is we continue to move at a very aggressive pace. I think everyone at PEPFAR needs to continue to move at that aggressive pace. I think, over the last three to 6 months, we have seen a real adjustment in the speed of work with the supply chain, with the countries, and with these elements in this inter-agency way.

Mr. SMITH. I know you, Ambassador, have to leave to go to the Senate side.

I do want to thank you again for your patience with that long interruption.

Your information and your leadership has been extraordinary.

We will follow up with this work together going forward. Obviously, it is all about helping victims.

The hearing is adjourned.

[Whereupon, at 3:39 p.m., the subcommittee was adjourned.]

A P P E N D I X

MATERIAL SUBMITTED FOR THE RECORD

SUBCOMMITTEE HEARING NOTICE
COMMITTEE ON FOREIGN AFFAIRS
U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515-6128

Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations
Christopher H. Smith (R-NJ), Chairman

May 10, 2018

TO: MEMBERS OF THE COMMITTEE ON FOREIGN AFFAIRS

You are respectfully requested to attend an OPEN hearing of the Committee on Foreign Affairs to be held by the Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations in Room 2172 of the Rayburn House Office Building (and available live on the Committee website at <http://www.ForeignAffairs.house.gov>):

DATE: Thursday, May 17, 2018

TIME: 1:00 p.m.

SUBJECT: Global Health Supply Chain Management: Lessons Learned and Ways Forward

WITNESSES: Ms. Irene Koek
Senior Deputy Assistant Administrator
Global Health Bureau
U.S. Agency for International Development

The Honorable Deborah L. Birx, M.D.
U.S. Global AIDS Coordinator
U.S. Special Representative for Global Health Diplomacy
U.S. Department of State

By Direction of the Chairman

The Committee on Foreign Affairs seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202/225-5021 at least four business days in advance of the event, whenever practicable. Questions with regard to special accommodations in general (including availability of Committee materials in alternative formats and assistive listening devices) may be directed to the Committee.

COMMITTEE ON FOREIGN AFFAIRS

MINUTES OF SUBCOMMITTEE ON Africa, Global Health, Global Human Rights, and International Organizations HEARING

Day Thursday Date 5/17/18 Room 2172

Starting Time 1:00pm Ending Time 3:39pm

Recesses 1 (1:14pm to 2:21pm) (to) (to) (to) (to) (to)

Presiding Member(s)

Chairman Smith

Check all of the following that apply:

Open Session ☒

Executive (closed) Session ☐

Televised ☐

Electronically Recorded (taped) ☐

Stenographic Record ☒

TITLE OF HEARING:

Global Health Supply Chain Management: Lessons Learned and Ways Forward

SUBCOMMITTEE MEMBERS PRESENT:

Ranking Member Bass, Rep. Garrett

NON-SUBCOMMITTEE MEMBERS PRESENT: (Mark with an * if they are not members of full committee.)

Chairman Royce

HEARING WITNESSES: Same as meeting notice attached? Yes ☒ No ☐

(If "no", please list below and include title, agency, department, or organization.)

STATEMENTS FOR THE RECORD: (List any statements submitted for the record.)

-Smith: Timeline of Recommendations for Nevirapine (NVP)-containing HIV treatment regimens

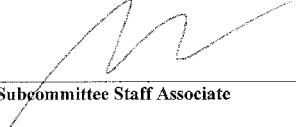
-Smith: Nevirapine Explainer May 2018

-Smith: Written statement by Chemonics International

TIME SCHEDULED TO RECONVENE _____

or

TIME ADJOURNED _____


Subcommittee Staff Associate

MATERIAL SUBMITTED FOR THE RECORD BY THE HONORABLE CHRISTOPHER H. SMITH,
A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY, AND CHAIRMAN,
SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, GLOBAL HUMAN RIGHTS, AND INTER-
NATIONAL ORGANIZATIONS

Timeline of Recommendations for Nevirapine (NVP)-containing HIV treatment regimens

2013 - Starting in 2013, the World Health Organization (WHO) recommended the combination of tenofovir disoproxil fumarate/lamivudine/efavirenz (TLE) or tenofovir disoproxil fumarate/emtricitabine/efavirenz (TEE) as a fixed dose combination tablet as the preferred first-line regimen for all adolescents and adults. Nevirapine (NVP)-containing regimens were recommended as an alternative first-line therapy if TLE (or TEE) could not be used.

2016 - The WHO published a revision and update of the ARV guidelines in 2016 after an extensive review of evidence and consultation in mid-2015. TLE (or TEE) remained the preferred first-line regimen recommended for all adolescents and adults, and dolutegravir (DTG)-based regimens were added as an alternative first-line option. However, there was no change in the recommendation for nevirapine formulations as an alternative first-line regimen. Both the 2013 and 2016 guidelines only addressed ARV-naïve patients; these guidelines did not provide any recommendation on switching patients currently on nevirapine-based formulations.

Consistent with the WHO's 2016 Guidelines, most countries list NVP-based regimens as an alternative rather than a preferred first-line for adults: two countries (Rwanda, Mozambique) list NVP-based regimens as a preferred first-line regimen option along with efavirenz (EFV)-based regimens.

2015 - 2018 - PEPFAR provided the following information in the Country Operational Plan (COP) guidance.

In COP 2015 guidance, reference to NVP was listed in the context of phasing out Option A/ single dose NVP. "Commodities considerations: Only ART should be procured for PMTCT; maternal AZT or NVP alone are no longer approved options."

In COP 2018 guidance: *Dolutegravir (DTG)-containing regimens are the preferred first-line antiretroviral therapies (ART) due to superior efficacy, tolerability and higher threshold for resistance compared to efavirenz (EFV)-containing regimens. The fixed dose combination (FDC) of tenofovir disoproxil fumarate/lamivudine/dolutegravir (TLD) is currently priced as the least expensive FDC, and it is expected that prices will go down as generic manufacturing scales up. For these reasons, PEPFAR now recommends TLD as the preferred option for ART, and further recommends that countries switch over to TLD as soon as possible in a coordinated fashion as supply becomes available.*

S/GAC and the agency headquarters will work with country governments and multilateral partners to support rapid adoption of TLD for adults and adolescents (>=30kg) currently receiving legacy first-line ARVs (including TLE, TEE, LZN) or ready to start ART. TLD is also encouraged for use as second-line (for patients failing an EFV- or NVP-based first-line regimen as well as those already receiving a protease inhibitor [PI]-based second-line regimen) in programs that can confirm virologic suppression within 3-6 months of transition.*

No countries should be using NVP-based regimens and PEPFAR will not fund NVP-based regimens.

*[*LZN = lamivudine/zidovudine/nevirapine]*

Dolutegravir Safety Notice

PEPFAR (S/GAC) is working with USAID-SCH to communicate the Dolutegravir safety notice and determine the impact on PEPFAR-supported countries as they transition to TLD. PEPFAR expects that countries will initiate their TLD roll-out as planned but roll-out plans will be adjusted to include temporary deferral of use of TLD for women who could become pregnant, pending analysis of additional data in 6-12 months. PEPFAR is providing assistance to country programs by forecasting the number of such women who will need to remain on TLE (or TEE) in the short-term. PEPFAR is also working to identify countries with minimal current first-line TLE (or TEE) stock on-hand and provide urgent assistance with forecasting additional procurement of these medications to prevent stock-out events.

GHSC-PSM (Chemonics) has placed orders for 21.5 million packs of TLD worth approximately US \$134 million dollars. These orders are for Uganda, Nigeria, and Zambia and will be delivered before the end of December 2018 in staggered shipments. As a result of the TLD safety issue, an additional order for 14.4 million packs of TLD worth approximately US \$90 million have been placed on hold until demand for TLD based upon updated supply plans can be determined.

The link for the PEPFAR statement on *Potential Safety Issue Affecting Women Living with HIV Using Dolutegravir at the Time of Conception* is below. The safety notification was published on Friday, May 18, 2018.

<https://www.pepfar.gov/press/releases/282221.htm>

WHO 2013 *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection* can be found at

http://www.who.int/iris/bitstream/10665/85321/1/9789241505727_eng.pdf?ua=1

WHO 2016 *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection; Recommendations for a Public Health Approach – Second Edition* can be found at

http://apps.who.int/iris/bitstream/10665/208825/1/9789241549684_eng.pdf?ua=1.



MATERIAL SUBMITTED FOR THE RECORD BY THE HONORABLE CHRISTOPHER H. SMITH,
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Nevirapine Explainer May 2018

Background on nevirapine and HIV drug regimens

Note: This document refers to the HIV antiretroviral treatment of adults and adolescents living with HIV. Pediatric formulations and antiretroviral treatment regimens for infants and children are not discussed at length, due to the unique circumstances and considerations for the treatment of infants and children such as the use and availability of different antiretroviral drugs, doses, administration, and formulations (e.g. liquids, powders, and granules), and other factors as children grow older.

Nevirapine (NVP)-containing regimens have been on the list of recommended first-line antiretroviral treatment (ART) regimens¹ for adult patients living with HIV since the World Health Organization (WHO) began publishing HIV treatment guidelines in 2002. Prior to 2013, both NVP- and Efavirenz (EFV)-containing regimens were recommended as first-line treatment regimens for patients starting treatment; no regimen was identified as being preferred.

In 2013, the fixed-dose combination of Tenofovir-Lamivudine (or Emtricitabine, a structurally similar drug to lamivudine and used interchangeably)-Efavirenz (TLE or TEE) achieved status as a “preferred” first-line regimen, less on the basis of overall superior efficacy compared to NVP as on the convenience of once daily dosing in a fixed dose combination with Tenofovir. Regimens containing NVP and other EFV-containing regimens were recommended as an “alternative” first-line therapy if TLE/TEE could not be used. Patients unable to use an EFV-based regimen due to side effects or because of a contraindication such as severe mental illness were switched to a NVP-containing regimen. From a clinical perspective, individuals on a recommended preferred or alternative treatment regimen, including those containing NVP, who achieve viral load suppression, are not failing treatment and are considered stable on an effective regimen.

The WHO treatment recommendations for first-line treatment regimens are for patients newly starting treatment. For patients who started on NVP-containing regimens following global or country treatment guidelines (most before 2013) and who are doing well on treatment, there has been no global guidance to actively switch stable patients on NVP-containing regimens to TLE. In some countries, patients who were stable on NVP-containing regimens have continued their regimen and not switched to TLE. Some stable patients have also opted to stay on their NVP-containing regimens based on personal preference. Patients found to be failing NVP-containing

¹ A combination of HIV antiretroviral drugs are required for the treatment of HIV. These combination regimens typically consist of three drugs from at least two active antiretroviral drug classes that form the basis of antiretroviral therapy (ART) for effective HIV treatment. While NVP, EFV, and DTG have been the focus of current discussions, the two other recommended antiretroviral drugs used in combination with NVP, EFV, or DTG to complete the HIV treatment regimen have also changed through the years.

regimens as determined through viral load testing and clinical assessment² should be switched to a second-line treatment regimen, not an EFV-containing regimen. EFV would not be appropriate in these situations since there is broad cross-resistance between NVP and EFV, such that resistance to one drug often produces drug resistance to the other even without prior exposure.

In the most recent WHO treatment guidelines updates released in 2016, TLE remains the preferred first-line regimen for patients starting HIV treatment and NVP- and other EFV-containing regimens remain alternative first-line regimens. New regimens containing dolutegravir (DTG) and a lower dose of efavirenz (EFV400) were introduced as additional alternative first-line treatments in the 2016 WHO guidelines as well. However, the WHO advised countries that there was insufficient data related to the safety and efficacy of using DTG or EFV400 among pregnant and breastfeeding women as well as individuals receiving concurrent treatment for tuberculosis and HIV.

NVP has also been an important drug used in the prevention of maternal-to-child-transmission (PMTCT) algorithms. Early in the HIV response, a single dose of NVP (sd-NVP) was used for pregnant women in labor in combination with time-limited courses of other antiretroviral drugs during pregnancy. However, the use of sd-NVP in these algorithms is now obsolete as treatment priorities have shifted to treating all people living with HIV with lifelong antiretroviral therapy (ART). Importantly, however, the use of NVP syrup for infants born to HIV+ mothers continues to be strongly recommended to prevent the transmission of HIV from mother to child.

Since the release of the 2013 WHO Treatment guidelines, TLE and TEE have become the most commonly used fixed-dose combination tablets currently in use for first-line treatment regimens, with 78 percent of patients on first-line ART in low- and middle-income countries currently taking TLE or TEE. The current national HIV treatment guidelines for 23 PEPFAR countries³, published between 2015-2017, have adopted the use of TLE/TEE as a preferred first-line regimen. The use of NVP-containing regimens has decreased and is reflected in the sharp declines in PEPFAR procurement for NVP-containing formulations, which has now been halted per the COP 2018 guidance issued in January 2018. However, until other alternatives such as DTG becomes widely available in countries, a small amount of NVP-containing regimens will be needed as an alternative first-line option to prevent disruption or delay of treatment for the small numbers of patients who are unable to take TLE/TEE in accordance with the 2016 WHO treatment guidelines.

² Viral load testing measures the amount of HIV virus in the blood. It is the standard of care to measure response to HIV treatment and is being scaled up in PEPFAR countries. Prior to the availability of viral load testing, other measures such as CD4 count, which indicates the degree of immunodeficiency, and clinical outcomes were used to assess response to HIV treatment.

³ Country guidelines reviewed for: Angola, Botswana, Burundi, Cameroon, Côte d'Ivoire, Democratic Republic of the Congo, Ethiopia, Ghana, Haiti, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Rwanda, South Africa, South Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe.

Transition to dolutegravir

Since 2016, and further with the transition to Tenofovir-Lamivudine-Dolutegravir (TLD) at the end of 2017, USAID's procurement of nevirapine has drastically decreased and been halted following the FY18 COP guidance and due to additional manufacturing capacity of TLE and due to the introduction of DTG and EFV400 as first line alternative options for the anchor drug. We recognize the benefits of TLD and are starting to transition countries to this regimen so that newly diagnosed patients and existing patients on nevirapine can be safely shifted to TLD, **as appropriate.**

We continue to have a small quantities of legacy nevirapine order scheduled for delivery for patients who are stable and have responded favorably to the regimen, as well as for those who may not be able to tolerate the current preferred first-line treatment regimen. The introduction of DTG has been highly anticipated due to its multiple benefits for patients, programs, and the impact on the HIV epidemic. It is recognized for being more effective at rapidly decreasing the amount of virus in the blood, better tolerated and easier to adhere to, more robust against developing resistance, and less expensive. These benefits, along with the potential to harmonize treatment using a DTG-containing regimen across multiple populations, are among the many reasons why DTG is viewed as an important drug in the HIV treatment toolbox.

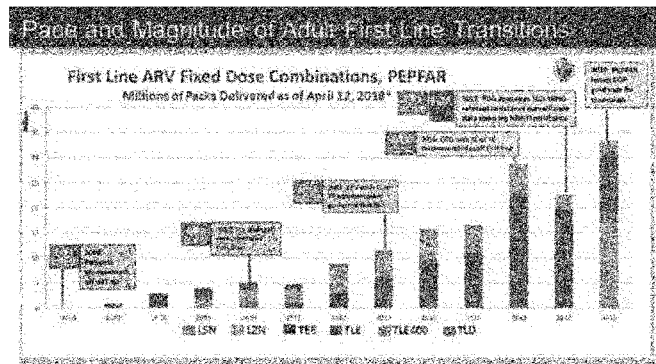
However, at the time of the 2016 WHO guidelines development, safety and efficacy data were not available for pregnant and breastfeeding women and individuals on concurrent treatment for tuberculosis and HIV. Up until last week, studies among pregnant and breastfeeding women appeared to be reassuring. However, on Friday, July 18, 2018, the FDA announced a new potential safety issue among women living with HIV using DTG at the time of conception (<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm608168.htm>). A preliminary unscheduled analysis of an ongoing observational study in Botswana reported four neural tube defects (birth defects of the brain, spine, or spinal cord) among 426 women who conceived while on DTG. This rate of approximately 0.9% compares to a 0.1% risk of neural tube defects in infants born to women taking other antiretroviral medicines at the time of conception.

From the same study, there is currently no evidence of any infant born with a neural tube defect to a woman who started DTG during her pregnancy. According to the manufacturer, prior studies which included embryofetal development studies in animals did not show evidence of adverse developmental outcomes. This finding is significant and serious, however additional data are necessary to further understand the safety of DTG use among women of childbearing age. USAID remains fully supportive of a safe and efficient transition to TLD for the appropriate patients and remains actively engaged in working with the Office of the Global AIDS Coordinator (SGAC) Short Term Task Team (ST3). This interagency working group is a group

of clinicians and supply chain experts from USAID, CDC and SGAC, mandated to rapidly facilitate transition to TLD effectively and efficiently, with the goal of ensuring the best outcomes for all patients PEPFAR supports.

We are working with countries to remove bottlenecks, train healthcare workers, and monitor the effects of the new medicines to identify and evaluate previously unreported adverse reactions.

Below is a graphic of the progress of guidance and purchasing of antiretrovirals.



**APPENDIX I: TIMELINE OF NEVIRAPINE USE AS RECOMMENDED
BY WHO HIV TREATMENT GUIDELINES AND PEPFAR COUNTRY
OPERATIONAL PLAN (COP) GUIDANCE AND TECHNICAL
CONSIDERATIONS DOCUMENTS**

(see Appendix 2 for full text excerpts from COP Guidances)

2010 (July 15 and 19) WHO 2010 HIV treatment guidelines released.

Summary

- Adults and adolescents
 - Recommended 1st line regimens: EFV- or NVP-containing regimen (with 2 other antiretroviral drugs)
 - No preferred 1st line regimen
- Pregnant women initiating lifelong ART (based on severity of immunodeficiency)
 - NVP- or EFV-based regimen, similar to other adults/adolescents
 - However, due to concerns on safety concerns of EFV in pregnant women, use of EFV during 1st trimester of pregnancy was not recommended

WHO 2010 First Line HIV Treatment Regimens for Patients Starting ART

Adults & Adolescents	Pregnant Women starting lifelong ART (based on severity of immunodeficiency)	Children and Infants
AZT or TDF <i>plus</i> 3TC (or FTC) <i>plus</i> EFV or NVP	AZT preferred but TDF acceptable <i>plus</i> 3TC (or FTC) <i>plus</i> NVP or EFV but do not initiate EFV during first trimester of pregnancy	Infant or child <24 months not exposed to ARVs: NVP + 2 NRTI Infant or child <24 months exposed to NNRTI: LPV/r + 2 NRTI Infant or child <24 months with unknown ARV exposure: NVP + 2 NRTI Children 24 months to 3 years: NVP + 2 NRTI Children >3 years: NVP or EFV + 2 NRTI

Abbreviations: 3TC=Lamivudine; AZT=Zidovudine; EFV=Efavirenz; FTC =Emtricitabine; NRTI=Nucleoside Reverse Transcriptase Inhibitors; NVP=Nevirapine; LPV/r=Lopinavir/ritonavir; TDF=Tenofovir disoproxil fumarate

2011 (August 2) **PEPFAR FY 2012 COP Guidance published (FY 2013 implementation). See Appendix 2, section on FY 2012 COP Guidance for full excerpt of references**

- Specific references to “NVP” or “nevirapine” are in the context of Prevention of Mother-to-Child Transmission (PMTCT) programs and includes language to shift away from the use of sd-NVP to triple therapy regimens recommended by WHO in 2010.
- NVP specifically mentioned in the context of infant prophylaxis for HIV-exposed infants.

2012 (October 1) **PEPFAR FY 2013 COP Guidance published (FY2014 implementation). See Appendix 2, section on FY 2013 COP Guidance for full excerpt of references**

- Specific references to “NVP” or “nevirapine” are in the context of infant prophylaxis for HIV-exposed infants.
- Guidance on PMTCT strategies focused on shifting away from Option A (ie, sd-NVP) to Option B or B+ (lifelong triple therapy)

2013 (June 30) **WHO 2013 HIV treatment guidelines released.**

Summary

Adults & adolescents:

- Tenofovir-Lamivudine-Efavirenz (TLE) or Tenofovir-Emtricitabine-Efavirenz (TEE) as a fixed-dose combination single tablet recommended as the ‘preferred’ 1st line regimen
- NVP-containing regimens and EFV in combination with other NRTIs become ‘alternative’ first line.
- Pregnant women:
 - TLE or TEE as a fixed dose combination
 - NVP-containing regimens and EFV in combination with other NRTIs become alternative.
 - Recommendation to initiate all pregnant and breastfeeding women with HIV on treatment. Option A no longer recommended.

WHO 2013 First Line HIV Treatment Regimens for Patients Starting ART

Adults & Adolescents	Pregnant Women	Children and Infants
Preferred: TDF + 3TC (or FTC) + EFV as a fixed dose combination Alternatives: AZT + 3TC + EFV AZT + 3TC + NVP TDF + 3TC (or FTC) + NVP	Preferred: TDF + 3TC (or FTC) + EFV as a fixed dose combination Alternatives: AZT + 3TC + EFV AZT + 3TC + NVP TDF + 3TC (or FTC) + NVP	Preferred: 3 yrs to < 10 yrs, and adolescents < 35 kg: ABC + 3TC + EFV < 3 yrs ABC or AZT + 3TC + LPV/r Alternatives: 3 yrs to < 10 yrs, and adolescents < 35 kg: ABC + 3TC + NVP AZT + 3TC + EFV AZT + 3TC + NVP TDF + 3TC (or FTC) + EFV TDF + 3TC (or FTC) + NVP < 3 yrs ABC + 3TC + NVP AZT + 3TC + NVP

Abbreviations: 3TC=Lamivudine; ABC=Abacavir; AZT=Zidovudine; EFV=Efavirenz; FTC=Emtricitabine; NVP=Nevirapine; LPV/r=Lopinavir/ritonavir; TDF=Tenofovir disoproxil fumarate

2013 (October 31) **PEPFAR FY 2014 COP Guidance published (FY2015 implementation). See Appendix 2, section on FY 2012 COP Guidance for full excerpt of references**

- Specific references to “NVP” or “nevirapine” are in the context implementing key WHO treatment recommendations (phasing out sd-NVP)
- References to “EFV” or “efavirenz” are noted in the context of the use of TLE in accordance with the WHO 2013 HIV treatment guidelines
- Other references to ARVs, specifically with regards to phasing out d4T (antiretroviral drug no longer recommended for use), and transition from AZT to tenofovir disoproxil fumarate (TDF) for first-line treatment, including discussions of renal toxicity associated with TDF and pharmacovigilance

2015 (January 9) **PEPFAR FY2015/COP15 Guidance published (FY 2016 implementation). See Appendix 2, section on FY 2015 COP Guidance for full excerpt of references**

- Specific references to “NVP” or “nevirapine” are in the context of phasing out Option A (ie, sd-NVP) . Commodities considerations include procuring only ART (ie, triple therapy), and maternal AZT or sd-NVP no longer being approved options.

2015 (December) **PEPFAR FY2016/COP16 Guidance published (FY2017 implementation). See Appendix 2, section on FY 2016 COP Guidance for full excerpt of references**

- No specific references to “NVP” or “nevirapine”

2016 (June 9) **WHO 2016 HIV Treatment Guidelines released.**

Summary

- TLE/TEE fixed dose combinations remain as preferred 1st line regimens
- NVP-containing regimens remain as alternative 1st line regimen options
- DTG-containing regimens added as alternative 1st line regimen option
- A regimen containing a lower dose of EFV (EFV400) also added as an alternative 1st line regimen option
- At the time of guidelines review, safety and efficacy data on the use of DTG and EFV400 in pregnant women, people with HIV/TB co-infection, and adolescents younger than 12 years of age were not yet available

WHO 2016 First Line HIV Treatment Regimens for Patients Starting ART

Adults & Adolescents	Pregnant Women	Children and Infants
<p>Preferred: TDF + 3TC (or FTC) + EFV as a fixed dose combination</p> <p>Alternatives: AZT + 3TC + EFV (or NVP) TDF* + 3TC (or FTC) + DTG TDF* + 3TC (or FTC) + EFV400 TDF* + 3TC (or FTC) + NVP</p> <p>*Safety and efficacy data on the use of DTG and EFV400 in pregnant women, people with HIV/TB coinfection and</p>	<p>Preferred: TDF + 3TC (or FTC) + EFV as a fixed dose combination</p> <p>Alternatives: AZT + 3TC + EFV (or NVP) TDF + 3TC (or FTC) + NVP</p>	<p>Preferred: 3 yrs to < 10 yrs, and adolescents < 35 kg: ABC + 3TC + EFV</p> <p>< 3 yrs ABC or AZT + 3TC + LPV/r</p> <p>Alternatives: 3 yrs to < 10 yrs, and adolescents < 35 kg: ABC + 3TC + NVP AZT + 3TC + EFV AZT + 3TC + NVP</p>

NOTE: The preceding document has not been printed here in full but may be found at <https://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=108119>

MATERIAL SUBMITTED FOR THE RECORD BY THE HONORABLE CHRISTOPHER H. SMITH,
A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY, AND CHAIRMAN,
SUBCOMMITTEE ON AFRICA, GLOBAL HEALTH, GLOBAL HUMAN RIGHTS, AND INTER-
NATIONAL ORGANIZATIONS

Global Health Supply Chain Management: Lessons Learned and Ways Forward
Submitted by James Butcher, Executive Vice President, Chemonics International

Thank you, distinguished members of the Committee, for the opportunity to submit this written testimony on behalf of Chemonics International and the USAID Global Health Supply Chain Program – Procurement and Supply Management (GHSC-PSM) project. My name is Jamey Butcher and I am executive vice president of Chemonics International. Since June 2017, I have been serving as the acting director of the GHSC-PSM project.

First, I want to acknowledge the fact that in the early days of administering GHSC-PSM, Chemonics did not live up to our own high standards, or yours. The entire Chemonics organization is committed to delivering to the American people and the communities we serve a high level of service and efficiency. To that end, immediately after we identified shortcomings in our performance, we agreed with USAID on an action plan to address project challenges. We began implementing that plan in April 2017 and completed it October 20, 2017. Since then, we have improved our performance and remain committed to continual assessment and improvement moving forward.

We recognize that Congress is a key stakeholder in the U.S. government investments in global health supply chains. We have appreciated the opportunity to share with Congressional staff the steps we have taken to correct performance issues and lay a foundation for success on GHSC-PSM. We especially appreciate the House Foreign Affairs Committee staff members who traveled to our project offices in Ethiopia and Uganda to see how our project works firsthand, meeting with governments, faith-based organizations, NGOs, and private sector organizations.

I would like to provide an overview of Chemonics and the award of the project, describe the transition from the preceding implementers to Chemonics, provide an overview of the project and how we identified challenges, and outline the action plan we developed with USAID and how we implemented that plan. Finally, I intend to provide you with an accurate picture of where we are today.

Before getting into these details, I'd like to emphasize that we are committed to our mission of helping people live healthier, more productive, and more independent lives. Ensuring people have access to medications when they need them is central to that mission. In all but a few countries, GHSC-PSM delivers primarily to central warehouses and not to the clinics or other service delivery points where patients get their medicines, and we conduct daily order prioritization and analysis to ensure that warehouses do not run out of product. While we deliver primarily to the central warehouse level, we monitor product throughout the supply chain to maintain visibility and ensure the health commodities are getting all the way to the patients who need them. Despite the challenges in our on-time delivery rates of health commodities last year, it's important to note that our analysis has not identified any evidence that patients were forced off treatment because of the project performance shortcomings.

Chemonics Overview and GHSC-PSM Award

Chemonics is a 100-percent employee-owned company that has grown from two employees when we began in 1975 to more than 4,600 today. However, the company's original focus on taking action to solve problems still holds true for all of us today. Part of our commitment to the communities we serve is to work collaboratively with them to tailor sustainable solutions to meet their needs. We provide extensive technical assistance and staff training in the countries in which we work. Over 90 percent of all field staff in our 32 field offices working on GHSC-PSM are nationals of the countries in which they work. That number is growing every day as we train more and more local partners to take on larger management and leadership roles. These trained and skilled local professionals can provide technical services to their countries for years to come, long after this project has ended.

The GHSC-PSM contract was awarded in April 2015. It is an indefinite delivery indefinite quantity contract, or IDIQ. This contract type gives USAID the option to issue task orders to Chemonics over the five-year performance period of up to the \$9.5 billion ceiling price. To date, USAID has awarded Chemonics five task orders with a cumulative ceiling of \$5.3 billion.

We administer these funds on behalf of USAID and ultimately on behalf of the American people. Over the life of the contract, more than 80 percent of the total GHSC-PSM contract value will be spent directly on commodities, which are a pass-through expense that Chemonics does not mark up in any way. We designed our approach this way to ensure cost savings and efficiencies that save the U.S. taxpayer money and expand the reach of the project.

The remainder of the GHSC-PSM contract value is dedicated to providing in-country technical assistance and supporting project headquarter operations. We share USAID Administrator Mark Green's vision of strengthening local country ownership and management to advance long-term sustainability. We believe in the importance of working ourselves out of a job, and this contract is no exception.

We take no fee, and we make no administrative overhead on any of the health commodities we procure or on the freight to ship or expenses to store them. That was not the case under the previous contracts. Instead, we only take a modest fee on the technical assistance portion of our work that is less than 2.5 percent of the technical assistance provided, and less than four tenths of a percent on the overall contract value.

Highlights from the Chemonics Proposal and Bidding Process

GHSC-PSM is the combination of two major projects, the Supply Chain Management System project (SCMS) and DELIVER. USAID rolled those projects into a single integrated supply chain, the first ever of its kind and scale in a global health program. This means that the U.S. government can achieve greater cost savings and economics of scale along with an unprecedented reach to people in approximately 60 countries that now have greater access to health commodities.

In 2011, Chemonics decided that administering this program on behalf of USAID would naturally fulfill our commitment to help people live healthier lives. A team of more than 60 Chemonics employees with backgrounds in supply chain management, global health systems, and other disciplines worked for more than three years to prepare for the proposal.

For a project of this size and scope, we knew we needed to find the best partners in a variety of complementary disciplines to assist in the overall scope, project design, and implementation. Our consortium originally consisted of a range of partners including IBM, Population Services International, and Kuchne + Nagel, a global leader in logistics. We later expanded the team to include nine other partners, three of which are classified as small businesses. Each consortium partner brings a distinct skillset and fulfills a unique role.

USAID rightly demanded that all bidders demonstrate the ability to procure and distribute commodities at or above the level of the previous implementers. We reviewed prior volumes of commodities delivered under USAID and reviewed each company's internal capabilities and prior experience in managing similar projects. We compared that to the historical data from SCMS and DELIVER and the requirements included in the GHSC-PSM proposal and determined that Chemonics and our consortium had the experience and capacity to do the job.

We knew that a state-of-the-art data system would be crucial to effective performance under the contract, so we invested our time and more than \$1 million in developing a prototype for our management information system, now called the Automated Requisition Tracking Management Information System (ARTMIS).

After submitting our proposal, we entered into the competitive review process, which consisted of two discussion rounds. The first lasted about two weeks and concluded with a 90-page initial response, which we submitted in October 2014. The second round occurred in late December.

On April 4, 2015, USAID notified us that it awarded Chemonics the contract. After several weeks of startup preparations, firms that previously worked on parts of USAID's supply chain contracts filed a protest. As legally required under the protest, a stop-work order was initiated and Chemonics postponed everything from hiring to planning to beginning the crucial work of building out the data systems. During this period, Chemonics retained all staff members who had been hired to administer GHSC-PSM, paying them with overhead funds.

The Transition Period

The protests and stop-work order took roughly eight months to resolve, from April to December of 2015. In late December 2015, our team resumed work. Our experience has always been that transitioning from one implementer to another is a relatively smooth process, one that occurs often in our industry. Unfortunately, this transition was more difficult.

The previous projects did not share the complete data we requested through USAID. As a result, GHSC-PSM could not populate our information management system with the information we needed.

Despite these challenges, Chemonics made significant progress and hit key milestones agreed to in the transition plan we submitted to USAID: we began transitioning field offices and processing procurements in February 2016; made our first routine commodity orders as planned in June 2016; began rollout of parts of our management information system; increased our staff from 12 to 225 in six months; held two strategic sourcing events; completed 1,500 shipping lanes; and completed our first deliveries.

Overview of the GHSC-PSM Project

GHSC-PSM has three major objectives:

1. *Commodity procurement.* The first goal, which constitutes the bulk of the project, is to ensure continued availability of quality public health commodities on time and at best value to save lives.
2. *Health systems strengthening technical assistance.* The second objective is to foster resilient and sustainable in-country supply chains to maximize the availability and management of commodities.
3. *Global collaboration.* The third is to engage partners throughout the world to promote adoption of global standards, commodity security, and the use of data for effective decision-making.

Our collective vision is for GHSC-PSM to substantially enhance the health care experience in the communities we serve through transformative supply chain solutions. We recognize that the challenges we face are not experienced by large, established commercial supply chains. We often deliver health commodities to areas with poor infrastructure, connectivity, and, at times, places where civil order has broken down. However, despite these differences, we are transforming the supply chain we inherited by pairing private sector practices with our social mission.

To accomplish this, we draw on the diverse expertise of our consortium partners and other partners all over the world to determine the best methods of operating a global supply chain. Working actively with governments, faith-based organizations, and other in-country partners, we collect data to understand each country's health commodity needs to ensure a consistent supply of health commodities. To complement this, we established a commodity security unit to systematically analyze ongoing commodity needs by using multiple data points to better understand the stock levels beyond the central warehouse to service delivery points throughout the country. This is vital because in all but a few countries, GHSC-PSM delivers primarily to central warehouses. From there,

an in-country supply chain managed by local governments, other donors, faith-based organizations, NGOs, and other entities takes over the process of delivering to regional warehouses all the way to service delivery points, such as hospitals and clinics.

Managing these in-country supply chains is a significant challenge for national and subnational governments and other stakeholders, so our teams provide on-the-ground technical assistance across 13 technical areas to help them create stronger in-country supply chains to the last mile. One critical area we support is helping improve forecasting and supply planning, because countries must be able to accurately predict, often more than a year in advance, the supply of antiretrovirals they'll need to treat HIV patients or the bed nets they'll need to prevent malaria. Based on these forecasts, in-country supply chains place orders with GHSC-PSM's global supply chain so that they will receive the right numbers of commodities at the right time. Our ultimate goal is to provide a continual feedback loop from the point of service all the way back along the supply chain so that orders are more efficiently and responsively matched to need.

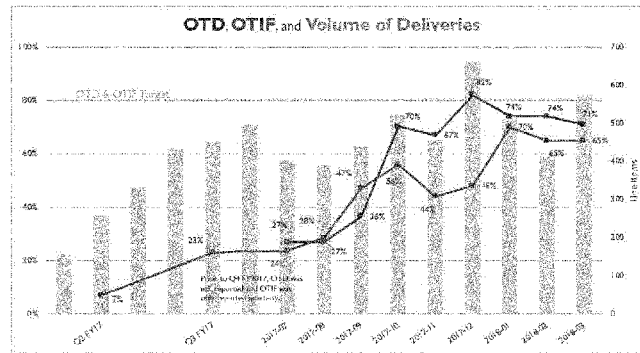
Identifying and Addressing Project Challenges

In early 2017, as data on the first quarter of health commodity deliveries was initially obtained, GHSC-PSM detected problems in our on-time and in-full (OTIF) delivery rate of health commodities, and we knew we needed to work closely with USAID to immediately address the issues. As shown in Graph A, on page 5, during this time, deliveries began to increase and challenges in our structure and processes hindered our ability to keep up with this increase and meet our OTIF targets.

The timeline below details when we first detected problems and our actions to improve project performance.

Date	Event
August 29, 2016	Launched the first release of ARTMIS, which included initial end-to-end supply chain management functionality.
October 2016	Delivered the first commodities procured by GHSC-PSM.
December 19 – 23, 2016	Launched the second release of ARTMIS.
January 2017	Initial data received from our first quarter of deliveries (October to December 2016) revealed delays.
January – March 2017	Increased the volume of commodities delivered, and FY2017 Quarter 2 data revealed a 7 percent OTIF rate.
March 8 – 16, 2017	Jamey Butcher, executive vice president of Chemonics, conducted a thorough top-to-bottom program review.
March 16, 2017	Presented to USAID an initial plan to address delivery problems.
April 3, 2017	Launched the third release of ARTMIS.
April 6, 2017	Replaced the global health supply chain director.
April 13, 2017	Received a memo from USAID noting performance challenges.
April 20, 2017	Chemonics committed a surge team of executives and other senior staff, as well as additional staff across multiple teams, to address systems enhancements to improve performance, at no extra expense to the U.S. government.
April 21, 2017	Submitted a response addressing USAID's memo and included a detailed action plan.
June 1, 2017	Removed the IDIQ director and replaced him with acting director Jamey Butcher.
October 1 – December 31, 2017	Reported on an additional metric for measuring global supply chain performance, on-time delivery (OTD), which reflects the current global supply chain's performance more accurately.
October 20, 2017	Addressed every item in the action plan developed in collaboration with USAID and detailed in the April 13 memo.
November 22, 2017	Published the Quarter 4 report, showing the project reached 47 percent OTIF in September. In October, achieved 70 percent OTD.
March 12, 2018	Published the fiscal year 2018 Quarter 1 report, showing the project reached 48 percent OTIF and 82 percent OTD in December 2017, and 72 percent OTD over the quarter.
May 17, 2018	Published the fiscal year 2018 Quarter 2 report, showing the project reached 67 percent OTIF and 73 percent OTD over the quarter.

Graph A.



Before we get into the specific ways we improved performance, I wanted to provide some context and detailed information about the metrics we use for on time delivery.

Measurement Criteria: On-time and In-Full (OTIF) Delivery and On-Time Delivery (OTD)

How and what we measure are critical to understanding this project and its performance. In the first year of the project, we primarily measured OTIF delivery. In fiscal year 2018, we began measuring OTD as well, giving us a real-time view into the global supply chain's performance. The difference between the two depends on when a late delivery is counted. With OTIF, a late delivery is counted in the month in which it was actually delivered. With OTD, a late delivery is counted in the month in which it was promised.

The way in which Chemonics applies the OTIF performance indicator is more stringent than the way our predecessors measured their performance. In the predecessor contracts, a supply was considered to be delivered on time if it arrived within four weeks (two weeks before and after) for SCMS and eight weeks (four weeks before and after) for DELIVER of the target delivery date. GHSC-PSM uses a three-week window (two weeks before and one week after) for all products. This three-week window for deliveries, while more challenging to achieve, is more representative of commercial benchmarks we strive to achieve as we continue to build a more and more efficient supply chain.

Improvement Plans

As soon as we determined our performance was below acceptable levels, we instituted plans to rectify the situation. One of our most immediate actions was to begin clearing the backlog of undelivered commodities. Addressing the backlog of undelivered commodities meant that they were delivered to their destination as quickly as possible, but it did nothing to improve our delivery metrics, since these orders were already late. Now that we are within our target indicator for backlogged orders, our OTD and OTIF performance metrics are improved as well. As of April 15, 2018, there were roughly 237 orders in our backlog, which is less than 5 percent of orders over the last 12 months.

In addition to clearing the backlog, the following is a list of actions we took (as outlined in our response memo to USAID submitted April 21, 2017) to improve performance:

1. **New leadership.** Recognizing the need for accountability and better governance, we replaced most of the leadership team, including the initial IDIQ director and the global supply chain director, and instituted a more responsive organizational structure.
2. **Created procurement efficiencies.** In addressing our supply chain management issues, we created a more efficient strategy and organizational structure for commodity procurement.
3. **Bridged gaps to country programs.** To improve visibility and increase responsiveness and transparency, we addressed gaps that existed between in-country offices and project headquarters.
4. **Expanded visibility and communication.** We streamlined communications to better align our staff and respond to requests for data by bringing our communications and monitoring and evaluation teams together.
5. **Improved reporting.** We reviewed and improved the depth and breadth of our reports to provide more clarity in evaluating ourselves in real-time, and allow us to be more responsive to requests for data.
6. **Expanded quantitative data collection and optimization.** We ensured that ARTMIS was the project's system of record and conducted user training worldwide.
7. **Increased operational efficiency.** We automated certain financial processes, and after a thorough risk management review, streamlined processes to reduce steps and delegate more authorities.

We completed all seven commitments that were outlined in our response to the April memo by October 20, 2017.

Elements to Improve On-Time Delivery

We also developed our own technical implementation framework to improve specific processes that allow us to avoid lapses in on-time delivery and detect warning signs quickly, as follows:

- **An Order Promise Tool.** One of the early challenges was setting delivery commitments inconsistently, not completely accounting for the complex nature of our supply chain, which may include 10 to 20 weeks of manufacturing production time with a supplier, eight weeks of quality testing prior to a shipment, three to six months to process a duty waiver so that a country does not tax our life-saving commodities, to name a few. We developed this tool, used by all local and commodity teams, to provide more realistic delivery dates.
- **An aggressive supplier management program.** Many suppliers were not meeting their on-time commitments to us. As a result, we initiated a program to ensure they improve their on-time commitment and provide timely paperwork, which is critical to downstream quality assurance, customs, and duty waiver processing. We continue to work to ensure suppliers uphold their agreements with us so that this important aspect of the supply chain does not cause late deliveries.
- **Daily prioritization of orders.** This is provided to each of our staff to ensure we are moving the most important orders with the most direct impact on our mission commitment dates. This daily prioritization is informed by the latest data from each country, where inventory may be running low. We also use a **visual early warning management system** to track and take quick action to address issues.
- **Decentralized procurement groups.** In nine countries, we established decentralized procurement to utilize the skills of our field-based staff, ensure we are responsive to the needs in each respective country, and employ an efficient means of procuring certain commodity types.
- **Streamlined sourcing and administrative processes.** In September 2017, we reorganized the global supply chain team so that procurement specialists own orders from start to finish, thereby reducing the time lost for hand-offs or administrative steps in the supply chain.
- **Strategic contracts.** Strategic contracts have been developed or are being pursued for several commodity groups to minimize the sourcing events that take place on every order, while also reducing commodity unit costs and response cycle times.

Current State

Since the start of the project through March 2018, we have procured more than \$1 billion in commodities for approximately 60 countries, established 32 field offices with more than 1,000 employees, and provided technical assistance in supply chain functions in 40 countries. On any given day, there are approximately 5,700 orders of life saving commodities in progress and on route to locations and the people who need them most.

As a result of the improvements implemented in 2017, as shown in Graph B, below, our overall on-time delivery rate has steadily improved at the same time the volume of our deliveries increased.

Graph B.

Summary of PSM Results Over Last Three Quarters			
Result	FY17 Q4 (July – September 2017)	FY18 Q1 (October – December 2017)	FY18 Q2 (January – March 2018)
On-Time Delivery	31%	72%	73%
On-Time In-Full Delivery	32%	49%	67%
Backlog at end of quarter	19.3%	4.8%	4.3%
Procurement	\$173.1 million	\$257.2 million	\$301 million
Value of deliveries	\$157 million	\$175.7 million	\$187 million
Number of line items delivered	1,151	1,844	1,500

Key Elements of the Supply Chain: Achieving Efficiency and Effectiveness

One reason it is difficult to benchmark GHSC-PSM's achievements is that there are few comparable supply chains, even in the commercial sector. The size of our shipments alone stands out. For instance, one January line item order represents 1.36 million malaria bed nets, which translates into 32, 40-foot cubic containers, or 25 football fields. This is one line item in our system, and on any given day, we are managing 5,700 such orders in our system. Below are a few examples of our approach to making this program as efficient and effective as possible:

- *Fourth party logistics (4PL) system.* Rather than partnering with a single sole-source logistics and warehousing company as was the previous practice, we use a 4PL system, bidding out key delivery lanes and crucial warehousing contracts to obtain best value in capability and cost. Generally, our average cost of freight per value of commodity is 4 percent. While there is no perfect comparison, Amazon runs between 5 and 15 percent, and the average health supply chain runs at 6 percent.
- *Strategic sourcing and market dynamics.* We seek the best possible pricing terms for the supplies we deliver by leveraging our market influence globally to understand market trends. We also perform in-depth analysis of the market dynamics that go into manufacturing medicines to better understand manufacturer price points. Using this analysis, GHSC-PSM has already generated significant cost savings and will continue to do so. For instance, the project has negotiated contracts that have yielded \$8 million in savings per year for an important HIV treatment, \$1.3 million per year for viral load tests, and \$1 million per year for malaria medication.
- *In-country supply chain optimization.* We focus on optimizing our in-country supply chains for greater efficiency and reduced costs. In Nigeria alone, we directly supported storage and transportation efficiencies that are projected to save \$2.3 million a year. And we project that the consolidation of our regional distribution network from five to three centers, one each in Belgium, United Arab Emirates, and South Africa, will save \$38 million over six years through reduced warehousing and transportation costs and decreased lead times for countries in need.

Preventing Stockouts

It is essential to avoid any circumstance where a patient goes without medicine. We've therefore adopted several mitigation measures:

- *We prioritize warehouse deliveries based on stock levels.* This means that when deliveries are late or there is a low supply at a central level, there are often still products at service delivery points where patients receive care. GHSC-PSM staff meet every afternoon to review this and make adjustments based on need.
- *We engage in forward planning.* As mentioned above, we engage in forecasting and supply planning at a country level, and use multiple data points and tools to understand stock levels below the central warehouse.

The Automated Requisition Tracking Management Information System (ARTMIS)

One major innovation we bring to create a robust global health supply chain is the development and rollout of ARTMIS, our state-of-the-art management information system. ARTMIS provides a catalog with more than 6,000 items provided by 325 suppliers across four major health areas. The system is designed to provide end-to-end, real-time visibility into the global supply chain to ensure immediate transfer of information and to enable evidence-based decision-making. In short, it offers three distinct advantages: 1) a user-friendly interface for ordering, 2) supply chain analytics to drive better decisions, and 3) a proven, off-the-shelf management information system hosted as a service.

The system is based on IBM's e-Commerce Suite, used by nine of the top 20 retailers in the world, and was developed in partnership with IBM to meet project requirements. It provides a number of advantages as a platform for data management, including enterprise-wide data quality assurance, and better-informed supply chain leaders. In addition, ARTMIS integrates with Kuehne + Nagel's logistics management information system and Chemonics' financial management information system to provide comprehensive supply chain logistics and financial information.

By automating key supply chain processes, ARTMIS provides the core functions to manage USAID's global health supply chain and gather timely information for accurate reporting from the supplier to the central medical store in each country. As the project progresses, we are expanding data visibility to regional warehouses and service delivery points, such as medical clinics in the country.

The core development of ARTMIS was completed in June 2017, on time, though the system had been taking routine order requests since April of 2016. GHSC-PSM has retired all manual trackers from operation. We are often asked when ARTMIS will be "finished," and the answer is – quite deliberately – never. We have a program of continual improvement, in which individual users can suggest system improvements, which are then evaluated and, if merited, built into an upgrade. This process of assessment and upgrade is constant, so ARTMIS is always improving and evolving.

Our strides in developing and using ARTMIS have allowed us a real-time view of the entire global supply chain to ensure that every dollar spent is delivering as intended and on schedule. Complementing ARTMIS, our financial management system gives USAID visibility into financials and generates monthly automated statements across all locations in which we operate.

Our Commitment

Despite the challenges and because of the improvements made over the past year, we are confident in our ability to uphold our commitments on this project and increasingly operate a global supply chain that reflects the performance of a commercial operation. Through incorporating commercial practices into all aspects of our work we are increasingly able to offer a more flexible, responsive, and efficient supply chain than previously accomplished by Chemonics or our predecessors. As we look ahead, the American taxpayer and U.S. government can be sure that we remain as committed as ever to substantially enhancing the health care experience in the communities we serve through our efforts on GHSC-PSM.

**Questions for the Record – Chairman Ed Royce
Global Health Supply Chain Oversight Hearing
May 17, 2018
Answered by Ambassador Birx**

Ambassador Birx and Deputy Administrator Koek:

Lessons Learned. It goes without saying that the implementation of this \$9.5 billion contract left a lot to be desired. I am glad we are finally seeing improvements. But for the future:

Q: Can you please describe the top three lessons learned from this contract whether it be from the awarding process, the transition or the implementation?

A: We have learned many lessons in this process. Three of the most important are:

1. We need a supply chain that is built for the 21st century. We have invested over \$3 billion in strengthening the supply chain since 2009 and we must ensure we are developing and supporting a system that has the resilience to meet the demands of today and tomorrow. This requires efficient and effective commodity forecasting, procurement and delivery, and tracking every product all the way down to the site where the client needs the medications or the diagnosis.
2. We need strong State Department's oversight of all PEPFAR-supported commodity procurements.
3. Weaknesses in the supply chain have real-life consequences in terms of whether someone shows up at the clinic for services or with how health care workers provide them.

Q: What changes have you made or do you plan to make going forward because of these lessons learned?

A: To ensure we are supporting a 21st century supply chain, we are working closely with USAID to address the weaknesses that have been identified over the course of this contract so that the supply chain can better deliver for the millions of patients that we serve. Moving forward, we must also consider if we are using the optimal conceptual framework for how to support a modern supply chain most effectively and efficiently.

The State Department has strengthened its oversight of all PEPFAR-supported commodities. For example, USAID now provides S/GAC with a monthly ARV Risk Report identifying countries that are currently experiencing potential or actual stock-out events. S/GAC also now approves any use of the Emergency Commodity Fund or the procurement of "legacy ARVs," once requests for these are initially vetted by USAID. In addition, S/GAC has directed USAID to halt further procurement of laboratory instruments based on the finding that most PEPFAR-supported countries are underutilizing their existing instrument capacity.

Late deliveries and other supply chain issues can have real consequences. No one wants to be down to their last test kit when a pregnant mother walks through the door and needs to be tested. So every clinic, every district hospital and every community site will begin to slow down services when they have concern about the arrival of key commodities. And patients may not come to the clinic if they perceive that the commodities they need will not be there when they arrive. Our hard work over the recent months has been to avoid these situations in the first place and to address them swiftly whenever issues do emerge.

**Questions for the Record – Chairman Ed Royce
Global Health Supply Chain Oversight Hearing
May 17, 2018
Answered by Ambassador Birx**

Improving Coordination. The more this Committee has investigated this, the more we have found there is a large disconnect and lack of coordination between the Office of the Global AIDS Coordinator and USAID and the CDC. Our investigation has revealed that the lines of responsibility and implementation of all global health programs are often unclear.

Q: How are PEPFAR funds divided and distributed? And which agencies are responsible for which aspects of our global health programs?

A: The PEPFAR Country Operational Plan (COP) is the basis for the approval and distribution of annual U.S. government bilateral HIV/AIDS funding in all PEPFAR-supported standard process countries. The COP outlines what specific investments will be made linked to specific implementing partners, budgets, and targets to ensure every U.S. dollar is maximally focused and traceable for impact. Once a COP is approved by S/GAC, PEPFAR implementing agencies are allocated funds in accordance with their respective roles, responsibilities, and implementing partners as designated in the COP.

In the planning, development, and implementation of the COP, S/GAC ensures that each agency has a defined and discrete role so the full U.S. government response in the country is well coordinated and non-duplicative. For example, USAID is responsible for providing support to the supply chain systems and the CDC is responsible for providing support to the laboratory systems.

Throughout the budget cycle, beginning with the COP planning process and continuing through its full implementation, PEPFAR implementing agencies are responsible for ensuring that their respective roles within the COP are consistent with the budget levels, policy guidance, and targets that were approved by S/GAC.

Q: How was this contract in particular affected by this lack of coordination?

A: I do not believe that a lack of coordination was a major factor in the underperformance of the global health supply chain contract. While there are always opportunities to improve coordination, both at the country level and at headquarters, we have developed strong systems of communications and coordination, including around the supply chain. Some examples of these systems include:

In calendar year 2017, S/GAC was instrumental in establishing the Integrated Diagnostic Consortium (IDC), which is comprised of the Global Fund, WHO, UNITAID, CDC, and USAID. The goal of the IDC is to ensure a coordinated, uninterrupted provision of timely, high-quality early infant diagnosis, viral load, and tuberculosis test results in countries most in need. The IDC is currently engaged with manufacturers on global reagent price negotiations, service contracts, and warranty standardization. The IDC is working with Cepheid for warranty improvements and an all-inclusive pricing list for its GeneXpert TB instrument and Abbott to reduce the unit cost for viral load and early infant diagnosis reagents.

S/GAC also engages with laboratory reagents and instrument manufacturers to address issues affecting PEPFAR procurement. For example, when manufacturers issue Field Safety Notices

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Answered by Ambassador Birx

that will affect testing in PEPFAR-supported countries, S/GAC engages directly with these suppliers in person and via phone to review and develop action plans to resolve the issue. S/GAC also issues official cables to affected PEPFAR-supported countries, providing informational updates and operational guidance on how best to address the issue.

At the country level, USAID works through the Partnership for Supply Chain Management (PSM). The CDC has laboratory advisors and laboratory staff in all PEPFAR-supported countries as well as some implementing partners with laboratory expertise. USAID and CDC work closely with their respective field teams to identify and resolve key issues. If a laboratory issue requires a higher level of engagement, the agencies elevate these issues to S/GAC, which then takes the lead and coordinates efforts to resolve it.

The TLD Short-term Task Team (ST3) was established in October 2017 to provide PEPFAR-supported countries with the best systematic and programmatic approach for the early adoption of TLD. S/GAC leads the ST3, which consists of interagency supply chain and clinical subject matter experts from the State Department, CDC, and USAID. The ST3 provides countries with strategic guidance on their transition to TLD, assists with the coordination of antiretroviral ordering within PEPFAR and across other funding agencies (e.g., Global Fund, KEMSA, South Africa and CDC), supports accurate commodity forecasting and quantification, and maintains visibility on market demands.

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Answered by Deputy Administrator Koek

Chairman Royce QFRs

Lessons Learned. It goes without saying that the implementation of this \$9.5 billion contract left a lot to be desired. I am glad we are finally seeing improvements. But for the future:

Q. Can you please describe the top three lessons learned from this contract whether they be from the awarding process, the transition or the implementation?

A. The design of the current supply-chain program was the result of extensive analysis from the previous 30 years of investments by the U.S. Agency for International Development (USAID) in logistics and procuring drugs, vaccines, and health commodities and supply chain. It also accounts for lessons learned from other organizations, including the United Nations Children's Fund (UNICEF); the Global Fund to Fight AIDS, Tuberculosis, and Malaria; and the private sector.

The first two years of implementation under the current program have already identified several key conclusions we will apply to the design of our next generation of supply-chain programming:

- While unifying our global supply-chain across health programs might have gained some efficiencies, it also increased our vulnerability, and reinforces the **need for strong risk-mitigation** measures in project-design, procurement, and management;
- **Strong leadership and management**, both by USAID and the winning contractor(s), is necessary to integrate consortium organizations successfully and quickly into a functional supply-chain program; we need to strengthen how we assess this during the procurement process; and
- Operating a large and complex supply-chain requires a robust, adaptable, and interoperable management-information system that is functional before the placement of the first order; we need **better ways to assess information systems** during the procurement process.

We plan to continue to look critically at the current program and contract in real time to improve implementation, and are also planning to commission an external evaluation of the program at the same time as we move forward to design its successor.

Q. What changes have you made, or do you plan to make going forward, because of these lessons learned?

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A. We have started to apply lessons learned aggressively to the design of next-generation supply-chain program of the U.S. Agency for International Development (USAID). We plan to undertake an external evaluation of the current program, and review its findings as part of the design process. Additionally, building on USAID's broader procurement-reform efforts initiated by Administrator Green, we are identifying ways to be innovative in the creation, procurement, and management of the resulting award.

We are also reaching out to the private sector to learn the most up-to-date models for procurement, monitoring, measurement, and how best to incentivize excellence and penalize poor performance among supply-chain providers. We will actively engage U.S. Government interagency partners, USAID field Missions, and implementers throughout the process for creating the next supply-chain program. We are committed to designing a program that will apply industry best practices, be efficient, minimize risk, and incentivize a high level of performance.

Improving Coordination. The more this Committee has investigated this, the more we have found there is a large disconnect and lack of coordination between the Office of the Global AIDS Coordinator and USAID and the CDC. Our investigation has revealed that the lines of responsibility and implementation of all global health programs are often unclear.

Q. How are PEPFAR funds divided and distributed? And which agencies are responsible for which aspects of our global health programs?

A. We defer to the Department of State's Office of the Global AIDS Coordinator.

Q. How was this contract in particular affected by this lack of coordination?

A. While coordination is always a challenge for any global initiative of this size and complexity, and critical to success, we do not assess that coordination issues were determinative factors in the performance of the contract.

The U.S. Agency for International Development (USAID) engages in multiple coordination structures led by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), both at headquarters and in the field. At headquarters, the Office of the Global AIDS Coordinator (S/GAC) at the U.S. Department of State, USAID, and the Centers for Disease Control and Prevention (CDC) within the U.S. Department of Health and Human Services (HHS) closely coordinate on matters related to the global health supply-chain through weekly meetings of Deputy Principals, Epidemic-Control Teams, and Short-Term Task Teams. These groups communicate on a routine basis, and set strategies for all PEPFAR-funded programs.

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The supply-chain program is particularly complex, and involves many stakeholders, both within and outside the U.S. Government, such as the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM); the World Health Organization (WHO); the HHS Food and Drug Administration (FDA); and partner governments. We continue to work together closely, and recognize there are always opportunities to improve communication and collaboration, both at the country level and at headquarters.

To improve this process, S/GAC created a Short-Term Task Team comprised of the lead U.S. Government clinical and supply-chain experts from the major PEPFAR implementing Departments and Agencies. The team has been operational for 10 months, in close collaboration with host-country leadership, U.S. Government PEPFAR country teams, manufacturers, and other donors, to plan and execute a expeditious, safe, and effective transition to a new first-line regimen for anti-retroviral (ARV) treatment, Tenofovir/Lamivudine /Dolutegravir (TLD).

In the field, PEPFAR country teams consist of representatives from USAID, S/GAC, HHS/CDC, and other Departments and Agencies, as applicable. Decisions pertaining to health programs are typically made in a collaborative and consultative fashion, in close coordination with partner governments. The teams work with Ministries of Health and implementers to quantify supply-chain and commodity needs at the national level in a way that accounts for all domestic and donor funding, program-specific stakeholders, and procurement sources and mechanisms (*e.g.*, national medical stores, the GFATM and the U.S. Government). For each country, this generally includes periodic collaborative review of supply plans to adjust for changes in consumption or projected demand.

Q. What is global industry standard for on-time delivery (OTD) and on-time-in-full delivery (OTIF)? Is this contract now meeting those standards?

A. One of the advantages of combining the two previous contracts into the current one was supposed to be streamlining the delivery of commodities by reducing confusion and duplication on the ground. However, since the metrics for the on-time delivery of these commodities changed from the previous contracts to the current one, it is difficult to do a true comparison.

We are not aware of set industry standards for on-time delivery (OTD) or on-time-in-full delivery (OTIF). Specific industries appear to have their own benchmarks, and businesses set their own targets. For example, according to an article published in July 2017 by [Bloomberg](#), Walmart's OTD rate was at 75 percent, while the company aspires to hit 95 percent within a four-day window.

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Only a few global public health programs are comparable to the Global Health Supply Chain – Procurement and Supply-Management (GHSC-PSM) contract. We selected 80 percent as the contractual target for OTD and OTIF for GHSC-PSM, as it aligned with the predecessor project's targets. The window is 14 days early and seven days late, or “-14/+7.” GHSC-PSM did hit 82 percent OTD in December 2017, and 72 percent overall for the quarter from October-December 2017. OTD for the most-recent quarter, ending in March 2018, was 73 percent, and OTIF was 67 percent, with variances for malaria, which we are working to address. The U.S. Agency for International Development (USAID) will not be satisfied until GHSC-PSM fulfills its contractual obligation of reaching a sustained OTD and OTIF of 80 percent.

Q. How do these delivery rates compare with other USAID contracts that involve the delivery of goods?

A. There are currently no comparable U.S. Agency for International Development (USAID) programs to the Global Health Supply Chain – Procurement and Supply-Management (GHSC-PSM) contract.

The predecessor projects used different metrics to calculate on-time delivery, including different delivery windows that ranged from four to eight weeks, rather than the three-week window set for GHSC-PSM. This means we are unable to make direct comparisons, but we have some indicative data. For example, the on-time delivery of the Supply Chain Management System (SCMS) for its four-week target window was below 80 percent for the first four years of operation, and then maintained around 80 percent in the last seven years. The DELIVER family-planning contract maintained an average of 90 percent on-time delivery, with a low of 62 percent in the third year of operation. The DELIVER malaria contract's on-time delivery was in the upper 70-percent range for the final three years, with a low of 64 percent in the fourth year.

Q. When were the OTIF parameters set for this contract? Was this the standard timeline that USAID follows for setting parameters following the start-up of a new contract? Why was the decision made to shorten the window for on-time-in-full delivery from what the previous contractor used?

A. The U.S. Agency for International Development (USAID) took the opportunity of launching a new project and contractor to review our supply-chain and technical-assistance indicators and strengthen their alignment with industry practice and Agency priorities. The Global Health Supply Chain – Procurement and Supply-Management (GHSC-PSM) consortium submitted a proposed performance-monitoring plan in May 2016. USAID and GHSC-PSM reviewed each of the proposed indicators, and agreed on the key performance indicators, including OTIF, which appear in GHSC-PSM's Monitoring and Evaluation (M&E) Plan, submitted in October 2016.

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USAID and GHSC-PSM established the final OTIF window of 21 days in January 2017. New indicators, with new definitions and measurement, meant that, in most cases, GHSC-PSM could not use the results from the predecessor projects as baselines to inform targets. For commodity-procurement and delivery indicators, USAID and GHSC-PSM finalized the targets in January 2018, after GHSC-PSM had completed a full year of procurement. The target for both OTD and OTIF is 80 percent.

Given the scope of the contract and the number of key performance indicators defined (40), the timeframe for developing the M&E Plan was within a normal range for a USAID contract.

As part of aligning with industry and Agency priorities, USAID shortened the on-time delivery window from -30/+30 days and -14/+14 days in the predecessor contracts to -14/+7 days in GHSC-PSM. This change reflected the greater efficiency in procurement and delivery the GHSC-PSM consortium promised.

Inspector General's recommendations. On March 31, 2017, the Office of the Inspector General for the U.S. Agency for International Development (USAID) made a number of recommendations concerning this contract in a report entitled, "Internal Control Concerns Regarding USAID Global Health Supply Chain - Procurement and Supply-Management Project (GHSC-PSM)," and on June 7, 2017, the Inspector General forwarded this Memorandum to the Acting Administrator. USAID responded on July 5, 2017, with an updated response on November 1, 2017. However, some issues remained outstanding at that time and are now being addressed within the broader plan to manage and mitigate risk under the GHSC-PSM contract.

Q. Has USAID begun directly employing independent firms to conduct annual or unscheduled audits of GHSC-PSM records, protocols and standard operations procedures? In your response on July 7, 2017, you indicated that USAID does not have the budget set aside for financial audits. Does your Fiscal Year 2018 budget request reflect a request for this funding? How much? If not, why not?

A. Yes, we are conducting independent audits of the Global Health Supply Chain – Procurement and Supply Management (GHSC-PSM) consortium through a variety of mechanisms. The Office of the Inspector General (OIG) for the U.S. Agency for International Development (USAID) is currently conducting two relevant audits, one on USAID's award process for the GHSC-PSM contract and USAID's management of the contract's global supply operation, and another on in-country supply chain weaknesses. For additional information on these audits and any other OIG oversight work, please contact the OIG directly.

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In addition, the Defense Contract Management Agency conducts audits of Chemonics' procurement system through a Contractor Purchasing System Review. The next audit is scheduled for March 2019. Finally, we are planning both external financial and data-quality audits after the OIG completes its audits, and we have set aside funding to pay for them.

Q. Have you hired a compliance officer/ risk-manager advisor dedicated to GHSC-PSM and/or completed the risk mitigation plan as mentioned in your July 7, 2017, response? If so, what new procedures is this risk-mitigation plan employing for this project?

A. We agreed with the Office of Inspector General (OIG) that strengthening risk-management is an important step in project management. While USAID has begun the recruitment process for a risk mitigation consultant, we continue to employ several risk management and mitigation activities as part of the agency's best management practice. USAID has established a rigorous management and oversight system to monitor project performance, identify risks and mitigate them, and provide strategic direction. USAID project management team uses several tools to monitor and mitigate risk. For example, maintaining an updated project monitoring and evaluation plan; routinely reviewing progress under 38 performance indicators, engaging USAID function leads in strategic management meetings with project leadership and staff; regularly reviewing orders to identify and manage the risk of early/delayed orders; monitoring progress and discussing updates of the project management information system (ARTMIS); thoroughly review quarterly performance reports; monitoring central stock status in country to identify and mitigate risk of stock-outs/product expiry at the central level and health facilities; and reviewing financial statements to manage financial risk and identify efficiencies. A risk management consultant is anticipated to be on board by August 2018 and will complement and improve upon USAID's already established project management and risk mitigation tools.

Q. The OIG recommends increasing the frequency of "spot checks" at end-use facilities and deploying random record-keeping inspections at centrally managed warehouses by floating USAID teams. Your November 1, 2017, update letter to the OIG suggests that you will begin a pilot program in high-risk countries to gain unscheduled access to warehouses and other sites. Has this pilot plan begun? In which countries? When will you report on this pilot program? Are there plans to expand it?

A. Yes, we are in the process of designing and launching a pilot program for high-risk countries. In addition to our regular monitoring (see below), through our risk-analysis (described in the question above), we plan to identify a high-risk country in which to start, and will work with the State Department and host-country governments to negotiate unscheduled access to warehouses

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and other sites. We will take lessons learned from this pilot and apply them to other high-risk countries.

As a part of routine monitoring, the U.S. Agency for International Development (USAID), through both USAID and contractor staff, conducts frequent spot checks at end-use facilities. For example, last year U.S. Government (USG) staff conducted over 1,000 site visits in the Federal Republic of Nigeria. Stock availability was one of the issues staff reviewed during these visits. In countries where diversion and lack of accountability have been consistent problems, such as Malawi, Nigeria, and Uganda, we increased our monitoring, and have raised concerns at high levels with the host government. In countries where these issues are persistent and remain unrectified, we have identified alternative ways outside the public-sector system to warehouse and distribute drugs and commodities purchased by the U.S. Government.

Rep. Garrett QFRs

Q. Please provide a list of individuals at Chemonics who were fired by Chemonics as a result of the failure to meet the requirements of this contract by Chemonics. What are their full names? When were they fired?

A. While the U.S. Agency for International Development (USAID) cannot direct Chemonics to hire and/or fire specific employees, Chemonics has responded to USAID's concerns through changes in personnel. With respect to the Global Health Supply Chain – Procurement and Supply-Management (GHSC-PSM) contract, USAID only approves key personnel in accordance with the key personnel positions and corresponding requirements found in the Indefinite-Delivery/Indefinite-Quantity contract and Task Orders (TOs). For example, Chemonics informed USAID on September 6, 2017, that the firm "...relieved the Project Director and the Global Supply Chain Director of their duties."

Q. Has there been any OIG review of USAID and PEPFAR decision-making and decision-makers as it relates to preexisting relationships with individuals at Chemonics? Any OIG review of the process of awarding this contract?

A. The Office of Inspector General (OIG) for the U.S. Agency for International Development (USAID) is currently conducting two audits on the global health supply-chain: one on USAID's award process for the GHSC-PSM contract and USAID's management of the contract's global supply operation, and another on weaknesses in in-country supply chains. For additional information on these audits and any other OIG oversight work, please contact the OIG directly.

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Q. Has anyone ever reviewed whether there were any pre-existing relationships between staff and leadership at Chemonics and the U.S. Government staff and USAID and PEPFAR prior to the awarding of this contract?

A. All staff who participated in the evaluation of proposals reviewed and consented to a Conflict-of-Interest (COI) Certification; by signing, they attested they had no disqualifying financial or employment interest with any of the bidders.

Staff also certified that they read and became familiar with FAR 3 .104, entitled "Procurement Integrity," and that they understood and completely observed the provisions of the regulation.

Q. Please provide a list of decision-makers who would have been responsible for the RFP process as it related to the \$9 plus billion awarded to Chemonics, by name?

A. Given the oversight role the House Committee on Foreign Affairs has over the U.S. Agency for International Development (USAID), we have provided descriptions to the Committee of the expertise and experience of those involved in the Technical Evaluation Committee for the Global Health Supply Chain – Procurement and Supply-Management (GHSC-PSM) contract. Below, we provide these descriptions again; this information is sensitive, and should not be disclosed beyond the Committee Members and staff.

- Professional with 35 years of experience in managing international development programs, organizational development, policy, and administration, including 25 years at USAID in a myriad of leadership roles in Africa and Washington, D.C., in both technical capacities and as a Contracting professional.
- Professional with more than 30 years of experience in project-management, budget, finance, procurement and logistics, including 15 years of field experience in a developing country while working with USAID and/or its programs. This experience includes nine years as a Contracting Officer's Representative (COR) at USAID for global health supply-chain programs.
- Professional with over 20 years of experience in international development, with the past 15 years dedicated to strengthening supply-chains for health programs in low- and middle-income countries. Experienced in multidisciplinary approaches to commodity-security; strategic planning; the design, award, and management of large-scale government contracts for goods and services; developing and supporting global initiatives and country programs; the monitoring and evaluation of projects, country programs, and multi-organizational initiatives; and coalition-building.

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- Technical adviser with 13 years of extensive programmatic expertise including in project-management and a range of global health programming. This includes four years as a COR at USAID as the primary technical manager of global health supply-chain programs.
- Professional with 10 years experience with population and reproductive health in the international development context, including four years overseas in the Foreign Service and seven years as a COR.
- Nearly 20 years of experience in the supply-chain field, including in supply-chain modeling; business intelligence and analytics; the assessment and design of supply-chains; using low-tech tools and scalable processes for supply-chain improvements in low-resource settings; conducted projects for supply-chain organization and consolidation, distribution-planning, and transportation strategy for government and retail clients.
- 20 years of professional experience in creating and managing health supply-chains and related initiatives in international food aid, food commodities, humanitarian assistance, global health, veterans' health systems, national science initiatives, infectious disease and reproductive health around the globe.
- More than 20 years' experience in working on the development, implementation and evaluation of programs on tuberculosis (TB) and the human immunodeficiency virus (HIV), including for the Office of the U.S. Global AIDS Coordinator at the U.S. Department of State.
- A certified supply-chain and project-management professional with more than 20 years of experience in every aspect of the management of information systems and the software-development life-cycle process with multiple U.S. Government Departments and Agencies, as well as the private sector; this includes over ten years of working specifically on supply-chain information systems that range from large Enterprise Resource Planning (ERP) systems for USAID's global supply-chain and several more-mature country supply-chains to moderately complex warehouse-management (WMS) and logistics-management information systems (LMIS).
- Over 27 years of professional experience in information and communications technology (IT), with a special emphasis on the management of IT programs and services; IT governance; and the development and modernization of enterprise applications, biometrics and identification systems, architecture, interoperability and standards— this includes serving as a senior advisor at USAID on global health programs, and working for large enterprises and U.S. Government Departments and Agencies that spanned diverse sectors, including telecommunications, financial, health, defense and development.

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Q. Do you have any idea the impact in human lives of a sub-500 OTIF?

- a. Do we know how many people aren't alive?**
- b. Do we have any type of quantifiable data on loss of human lives?**

A. No, we do not have any conclusive evidence or data on loss of life as a result of the contractor's performance.

On-time delivery (OTD) and on-time-in-full delivery (OTIF) are two of 40 indicators the U.S. Agency for International Development (USAID) uses to manage and provide oversight of the Global Health Supply Chain – Procurement and Supply-Management (GHSC-PSM) contract. They measure the performance of procurement and delivery, and are not indicators for stock-outs at the point of care.

Our primary concern is ensuring access to life-saving medicines and prevention measures for those who need them. USAID, has been working diligently, in Washington and the field, to ensure the poor performance of the GHSC-PSM consortium does not put people at risk. We have been monitoring inventory levels in countries, and reviewing shipments, product by product, country by country, to identify the risk of stock-outs and mitigate that risk through several strategies, including by coordinating with other donors to cover gaps; prioritizing shipments across countries; redistributing available stock in country; and, where appropriate, substituting similar products.

Through the technical assistance USAID provides at the country level, we have worked to establish levels of resilience in host-country supply-chains that mitigate risk and limit the impact of delays in deliveries, which can arise from any number of factors. For example, we work with partners to create buffer stocks, and improve good inventory-management at national central medical stores, which should enable programs to continue to operate and provide needed medicines for a period from three to nine months while awaiting the arrival of an order. For example, data from Zambia are showing the availability of products at health facilities is quite high--between 90 and 100 percent, depending on the product— while OTD to Zambia has ranged between seven and 55 percent. This indicates the impact of late deliveries by the project was minimal, although any failure to meet the performance standards of the GHSC-PSM contract is unacceptable.

Through these efforts we have minimized the impact on those our programs serve, but we know of two exceptions. In the Federal Republic of Nigeria, late delivery by GHSC-PSM delayed campaigns to distribute mosquito nets in two States. Campaigns typically take place every three years, the average life of a mosquito net; delays could mean that families might not be protected

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by sleeping under a fully functional net. USAID worked with in-country partners and Chemonics to minimize the delays to two months or less. USAID also changed its procurement policy to reduce the number of different nets we procure by limiting the allowed specifications. With the change in policy, we expect to see a reduction in cost and lead times, and more interchangeability of nets across countries, which would help in situations like the one in Nigeria. We should point out that this policy work was already in development when we learned of the problem with the delivery of nets in Nigeria, and was not a direct response to this delay.

In Ukraine, GHSC-PSM procurement challenges delayed the President's Emergency Plan for AIDS Relief (PEPFAR) from scaling up the treatment of new patients for three weeks, which affected the ability of the U.S. Government country team in Ukraine to reach PEPFAR targets. Only one-third of new patients were able to start treatment as originally scheduled, but we understand patients who were already on treatment with the delayed product faced no additional risks.

Q. Do we have any way of knowing the number of people who might have been infected by failure of delivery?

a. Do we have any idea the number of children who might have been born with HIV due to the failure of Chemonics to deliver?

A. No, we do not have data or evidence to correlate any delays to infection rates. The U.S. Agency for International Development (USAID) is only aware of two instances in which the late delivery of products by the Global Health Supply Chain – Procurement and Supply-Management (GHSC-PSM) consortium had a programmatic impact and thus affected the well-being of those we serve. In the Federal Republic of Nigeria, the late delivery of mosquito nets resulted in the delay of distribution campaigns in two States. In Ukraine, late deliveries forced the President's Emergency Plan for AIDS Relief to delay the initiation of HIV treatment for new patients for three weeks.

Q. Can USAID provide a plan of action moving forward as to how you're moving forward to correct these issues in the future?

A. In response performance concerns, in April of 2017, the U.S. Agency for International Development (USAID) demanded that Chemonics develop and implement an action plan to address its deficiencies. The actions in the plan included shifting to full use of the Global Health Supply Chain – Procurement and Supply-Management (GHSC-PSM) consortium's management-information system (MIS), restructuring GHSC-PSM's global supply-chain operations, and transitioning to the new network of regional distribution centers (RDC). Chemonics completed the actions in the plan at the end of 2017, and this led to improvements in the consortium's on-

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time in-full delivery (OTIF) rate from seven percent at its lowest to 67 percent for the quarter ending March 2018. On-time-delivery (OTD) reached 73 percent for the same quarter.

As the consortium's performance on malaria continued to be low, USAID demanded a second plan to improve OTD and OTIF for malaria. That plan focuses on improving the management of the performance of suppliers, a daily review of malaria OTD and OTIF projections and actions to remediate any delays, improving procedures to limit hand-offs between teams, strengthening the management of logistic providers, and more-strategic use of the Regional Distribution Centers (RDC) for malaria orders. The consortium is currently implementing the plan, and provides USAID with weekly updates on progress.

Finally, we are applying the lessons learned from this experience to the design of the next supply-chain program.

Rep. Smith's QFRs

Q. Can you quantify the extent of USAID's bureau wide partnership with Chemonics International (or its affiliates and subsidiaries) in terms of:

- **Number of contracts:**

A. Chemonics holds 75 out of a total of 3,888 active awards across portfolio of the U.S. Agency for International Development (USAID).

- **Dollar amount all such contracts:**

A. The total estimated amount of all Chemonics' active USAID awards is \$7,736,787,938.19. Note that this amount is the **maximum** amount the Agency may obligate, and there is no guarantee any award will be fully obligated. Of this amount, \$5,280,788,939.00 is attributed to the five Task Orders under the Global Health Supply Chain – Procurement and Supply-Management (GHSC-PSM) consortium. Removing the total estimated amount of the GHSC-PSM Task Orders, the total estimated amount of active USAID awards held by Chemonics is \$2,455,998,999.19.

- **What percentage of all USAID contracts are with Chemonics:**

A. Chemonics holds 1.9 percent of all USAIDs active awards.

Q. Has anyone inside or outside of USAID expressed concern with overreliance on Chemonics?

a. **Who?**

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A. Broadening the partner base of the Agency is the cornerstone of the Effective Partnering and Procurement workstream of USAID's transformation. The concentration of USAID's portfolio of grants, contracts, and cooperative agreements in a small number of implementers is a systemic risk to the Agency: In Fiscal Year 2017, just 25 organizations were the recipients of 60 percent of USAID's spending on acquisition and assistance (A&A), Chemonics among them, and 75 organizations were responsible for 80 percent of the Agency's total A&A investments. The Transformation's efforts on procurement-reform are not about any one implementer, however.

b. What was said?

N/A

c. How has USAID responded to such concerns?

N/A

Q. Were there reports from the field regarding past poor performance by Chemonics, such as from Ethiopia? Was that taken into consideration in awarding the contract?

A. The U.S. Agency for International Development (USAID) evaluated the past performance of relevant and recent projects of both offerors during the review of the bids for the Global Health Supply Chain – Procurement and Supply-Management (GHSC-PSM) contract. The past-performance reports pulled for Chemonics included the following:

- 1) The Famine Early-Warning System Network (FEWS NET, a global project);
- 2) Malawi Indoor Residual Spraying;
- 3) Philippines Private-Sector Mobilization for Family Health;
- 4) Kenya Pharma; and
- 5) The Rwanda Family Health Project.

We have previously shared these reports with the Committee.

Q. In addition to quarterly reports regarding Chemonics performance, are you receiving monthly reports? If not, why not?

A. When the performance issues began, we asked for, and now receive, reports on a weekly basis. Chemonics reports on-time delivery (OTD) and on-time-in-full delivery (OTIF) on behalf of the Global Health Supply Chain – Procurement and Supply-Management (GHSC-PSM) consortium on a monthly basis, both overall and by health element and product. We also receive

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a daily dashboard that tracks the status of orders and highlights any delays in the procurement and delivery process that might affect delivery.

Q. You testified that, during the bid process, input was solicited from the field. Did any field representatives serve on the Technical Evaluation Committee that reviewed the bids?

A. The U.S. Agency for International Development (USAID) solicited input from U.S. Government field staff during the design process. For example, the design team launched a 38-question survey, which generated responses from 77 field staff in 29 countries from USAID and the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services.

In addition, people with field experience participated on the Technical Evaluation Committee (TEC). A Foreign Service Limited Officer who served as a commodities advisor participated in the TEC while on detail to Washington from the field. Other members of the TEC had worked overseas on U.S. Government health and development programs, including one who served for 15 years as a Foreign Service National prior to being posted in Washington.

Q. If not, why not?

N/A

Q. Are there any structural impediments, such as loss of compensation, to field representatives serving on the TEC?

A. While there are no formal impediments, such as loss of compensation, it is difficult for field representatives to be away from their job for the extended period of time necessary to participate on a Technical Evaluation Committee (TEC) for a complex award. Missions are typically short-staffed, and find it challenging to cover all of their responsibilities in the best of times, so they are often reluctant to release staff for long periods.

Given the size of the Global Health Supply Chain – Procurement and Supply-Management (GHSC-PSM) contract, the TEC meetings took place over a period of 13 months, which, in some cases, is approximately half of the time a Foreign Service Officer served at an overseas Mission. Further, because of the sensitivity of the procurement process, TEC members were sequestered together for several months, away from their normal work space, during the review of the technical proposals, and were not allowed to communicate about the review via email. All of this made remote participation logistically infeasible.

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If so, what steps has USAID taken or will take to remove such impediments?

A. The U.S. Agency for International Development (USAID) will continue to seek field-based perspectives for both the design and evaluation process for the next procurement.

Q. You testified “best practice” measures were taken before an award was made in the matter under review. Did your practice include in-person presentations, or allow for live questions and answers?

A. The U.S. Agency for International Development (USAID) invited all interested parties to attend an “industry day” to help inform the design of the Global Health Supply Chain – Procurement and Supply-Management (GHSC-PSM) program. The industry day included questions from companies, and we received significant feedback. While Part 15 of the Federal Acquisition Regulations does permit use of oral presentations, there are a number of considerations to take into account when determining if they are appropriate and will streamline a procurement.

Q. Did your practice include a demonstration of the information-technology (IT) system?

A. Our solicitation did not require an IT demonstration. Section M of the solicitation stated that the Agency would evaluate offerors based on “the degree to which the offeror demonstrates capability, quality, and appropriateness of the proposed information system(s).” Offerors were required to describe the applicability of their current systems to the supply-chain services, and to also describe the manner and timeline in which they could modify their systems to match the scale of the required work. The U.S. Agency for International Development (USAID) did use two IT advisors as resources to the evaluation panel, who had more than 40 years of combined experience; one of them previously worked in the Office of the Chief Information Officer at the Agency. These IT advisors took into account that Chemonics’ proposed system was comprised of three, existing, functioning systems with strong capabilities, two of which, IBM and Kuehne + Nagel (K+N), are highly renowned. More specifically, several private-sector entities had used IBM’s system, e-Commerce, including the two largest distributors of health products in the United States. The K+N system processed 1.5 million monthly shipments, with 20,000 active customers. The third was Chemonics’ own financial system, which had been in operation for many years, and managed substantial dollar amounts. These existing systems were considered a strong foundation for the scalability required under the solicitation. At the same time, it was clear the existing systems of each of the offerors were going to require further integration and scalability after award.

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We would like to take this opportunity to clarify that having a fully integrated system already at scale was not a prerequisite for organizations to bid for the Global Health Supply Chain – Procurement and Supply-Management (GHSC-PSM) contract, given the significant up-front costs that could have been a barrier to competition. Moreover, the utility of any such demonstration would have been limited, because USAID had not conducted “blueprinting,” a requirements-gathering exercise regarded as an industry best practice that ensure IT systems align and support an organization’s business needs. Either offeror’s IT system would have required “blueprinting.”

Q. Are such presentations and demonstrations common practice in the private sector?

A. Allowing presentations/demonstrations is a business decision, and management must take into account a variety of factors before opting to use them, including cost, the utility of such presentations in making an award decision, and the type of good/service being procured.

Q. What about in other government procurement agencies?

A. The use of a demonstration/presentation depends on each Department or Agency’s needs and specific requirements, and the complexities associated with each procurement. Over the years, the Federal Government has used oral presentations to varying degrees as a means for evaluating an offeror or a specific element of a requirement. However, we do not have data on how often other Departments and Agencies use presentations in their review of bids.

Q. If these practices were not observed, is it fair to say that USAID took “best practice” measures?

A. During the design phases, the U.S. Agency for International Development (USAID) commissioned an external evaluation, solicited input from U.S. Government field-based country teams, and reviewed industry practices. As a result, USAID took into account best practices in preparing the solicitation and evaluation of proposals. Every procurement is unique, and oral presentations might not be a best practice for every procurement.

Q. You testified that your supply-chain team works with USAID’s clinical and scientific experts, as well as with OGAC, HHS and CDC.

How do you ensure that Country Operational Plans (COPs) are implemented throughout the supply chain?

A. All U.S. Government Departments and Agencies, partner governments, public international organizations (PIOs), and civil-society organizations involved in the President’s Emergency Plan

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for AIDS Relief (PEPFAR) actively participate in the annual Country Operational Plan (COP) meetings. The Office of the Global AIDS Coordinator (OGAC) issues annual guidance for the standard process for reviewing and approving COPs. Each country's COP, as submitted by U.S. Government country teams, undergoes a thorough review and vetting by all parties involved that follows the set process. The review includes, but is not limited to, program goals, components, activities, targets, the management and performance of partners, commodities, quality-assurance, the collection and analysis of data, potential barriers, coordination, communication, budgets, financial monitoring, etc. PEPFAR partners then implement approved PEPFAR supply-chain activities, with coordinated oversight and management by the interagency PEPFAR country teams and support from headquarters.

Q. How do you account for Nevirapine being distributed?

A. The 2016 edition of the World Health Organization (WHO) *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection* currently recommends anti-retroviral (ARV) therapy regimens that contain Nevirapine (NVP) as alternative first-line treatment for adults, adolescents, and children above three years of age. This most-recent version of the *WHO Guidelines* also list NVP-based regimens as the only recommended treatment option for very young infants (less than 14 days old).

Starting with Country Operational Plans (COPs) in Fiscal Year (FY) 2012, the Office of the Global AIDS Coordinator (S/GAC) has issued guidance every year that has discouraged the use of single-dose NVP for the prevention of mother-to-child transmission (PMTCT), and has recommended instead starting all HIV-positive pregnant women in PMTCT programs on life-long triple-drug ARV therapy. Consistent with WHO treatment guidelines and COP guidance, current country guidelines in 23 countries¹ under the President's Emergency Plan for AIDS Relief (PEPFAR) recommend life-long ARV therapy for HIV-positive pregnant women, and the U.S. Agency for International Development (USAID) no longer procures NVP for single-dose use in PMTCT programs.

At the time of the release of the COP guidance for FY 2018 in January 2018, S/GAC recommended that all adults and adolescents (10 years old or older and weighing 30 kilograms or more) remain on a legacy first-line regimen, including NVP-based combinations, until the full transition to Tenofovir/Lamivudine /Dolutegravir (TLD). The COP guidance also encouraged transition to TLD as a second-line treatment regimen for patients who are failing an Efavirenz (EFV)- or NVP-based first-line regimen, and for those already on second-line regimens based on a protease-inhibitor in programs where virologic suppression could be confirmed within three to six months of transition. Immediately after the release of the COP 2018 guidance in January 2018, USAID has stopped placing NVP orders as part of the global transition to TLD.

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There are several clinical scenarios in which the ongoing use of NVP could be in the best interest of a patient and safely continued:

1. For patients unable to take Efavirenz because of side effects or other clinical contraindications, the only cost-effective alternative first-line drug currently available in most countries is NVP;
2. Patients who started on NVP-based regimens in the past and remain virologically suppressed; these patients demonstrate that they are responding to an effective treatment regimen, and may safely continue taking it as long as they do not develop side effects, or become unstable; some patients do prefer to stay on their Nevirapine-containing regimen for a number of reasons, including comfort with a regimen they have been on for years, being wary of taking a new drug, or other personal reasons;
3. Given the new concern regarding the potential safety of the use of dolutegravir in women at the time of conception, women who are unable to tolerate Efavirenz might need to continue using a NVP-containing regimen even as TLD becomes available.

In all cases, if patients are not virologically suppressed and are experiencing treatment failure on a NVP-containing treatment regimen, they need to be switched to an effective second-line treatment regimen (*i.e.*, not an Efavirenz-containing regimen).

The most-recent national HIV treatment guidelines for 23 PEPFAR countries¹, published between 2015-2017, have adopted the use of the WHO-recommended Tenofovir-Lamivudine (or Emtricitabine)-Efavirenz (TLE/TEE) combinations as the program's preferred first-line treatment. Since alternative treatment options must be available for individuals who are unable to tolerate Efavirenz, many countries currently allow regimens that contain NVP as a substitute for these patients. While NVP-based regimens are no longer the preferred first-line regimen for patients who are starting ARV treatment financed by PEPFAR, the formulations remain very efficacious, and the WHO continues to recommend them as an alternative regimen.

Until other alternatives such as dolutegravir become widely available in the developing world, a small amount of NVP-containing regimens will be needed as an alternative first-line option to prevent the disruption or delay of treatment for the small numbers of patients who are unable to take TLE/TEE, in accordance with the 2016 WHO treatment guidelines. Different formulations of NVP exist, to allow for flexibility in developing an appropriate treatment regimen for an individual patient. Given the number of combinations of drugs with which NVP may be used,

¹ Country guidelines reviewed for: Angola, Botswana, Burundi, Cameroon, Côte d'Ivoire, Democratic Republic of the Congo, Ethiopia, Ghana, Haiti, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Rwanda, South Africa, South Sudan, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe.

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both the fixed-dose combination formulation of Lamivudine-Zidovudine-Nevirapine, as well as the single-tablet Nevirapine formulation used as part of a triple-drug ARV treatment regimen, could be needed for patients who require an alternative first-line regimen.

It is important to note that other donors, chiefly the Global Fund to Fight AIDS, Tuberculosis, and Malaria, and country governments also procure ARVs for PEPFAR countries. Since PEPFAR guidance does not bind other donors and national governments, which base their procurement on a country's national guidelines, these organizations continue actively to procure and deliver NVP-based regimens to countries.

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1. You are missing PEPFAR country coordinators in key countries.
 - a. How has this affected performance and ability to coordinate with USAID and conduct oversight?

The PEPFAR Country Coordinator (Coordinator), as a representative of the U.S. Embassy front office and S/GAC, ensures that all PEPFAR implementing agencies follow S/GAC guidance and provides overall financial oversight and monitoring of all PEPFAR-supported efforts in their respective country. The Coordinator is uniquely positioned to ensure all PEPFAR implementing agencies are utilizing the best available data to drive the greatest possible impact through the development and implementation of an accountable and transparent country operational plan.

The absence of Coordinators in several key locations impedes S/GAC's ability to fulfill its critical financial oversight and monitoring functions as well as to ensure close coordination across PEPFAR implementing agencies to drive optimal program performance. It also has placed an additional burden on many team members throughout the organizational structure as they attempt to fill the void created by these vacancies.

- b. What is being done to address this?

I have discussed the large number of vacancies, including of PEPFAR Country Coordinators, with Secretary Pompeo. The Secretary has initiated a process to examine S/GAC's vacancies and review the available options for addressing critical staffing gaps, including those created by the previous hiring freeze at the Department of State.

2. It seems that one problem affecting our global health policy is that the different US government agencies involved are not coordinating their efforts effectively.
 - a. For example, in Ethiopia there was a lack of rapid test kits at the facility level, despite the fact that there were sufficient stocks in country. USAID's supply chain contract consistently documented availability; however, the responsibility for getting them out to the facility level was that of the Government of Ethiopia, CDC's partner. Does OGAC have the ability to hold CDC accountable, and if so, what did OGAC do to hold the CDC accountable?

SGAC has the ability to hold all U.S. government agencies accountable for the programs that they implement in Ethiopia. In the case of the Government of Ethiopia (GOE) procurement and distribution of rapid tests kits (RTKs), this process is not

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only supported by CDC. The Global Fund to Fight AIDS, Tuberculosis and Malaria (GF) procures rapid test kits (RTKs) in Ethiopia and the GOE through its Pharmaceutical Fund and Supply Agency (PFSA) is responsible for their distribution. PEPFAR coordinates with the GF to ensure that adequate RTKs are procured and with the GOE to ensure that RTKs are distributed appropriately in the country. In the last year, PEPFAR has eliminated its provision of technical assistance around HIV testing to the GOE in non-priority geographic areas of the country. This decision is a result of the GOE continuing to distribute RTKs throughout the entire country instead of aligning their distribution to priority sites in high-HIV-burden areas, which would be more impactful and cost-effective. This untargeted distribution of RTKs is a key factor in some sites reporting stock-outs of RTKs.

In addition to the GOE over-testing in non-priority areas (areas with little-to-no HIV burden), the GOE also continues to over-test among non-prioritized population groups. Based on the latest epidemiological and program data, PEPFAR has shifted its focus in Ethiopia and only supports targeted HIV testing strategies aimed at priority and key populations in the highest disease burden areas. We continue to engage with the GF and GOE, which are largely responsible for determining the distribution of RTKs in the country, to adopt and implement more targeted testing strategies.

It is also important to note that RTKs are the only HIV-related commodity that is not in the national Integrated Pharmaceutical Logistics System (IPLS). PEPFAR continues to advocate for the inclusion of RTKs in the IPLS, as it would allow for greater visibility on the availability of RTKs, including at the facility level, and help reduce stock-outs. In the interim, PEPFAR has developed a messaging system called IVR that allows sites to report on their RTK stock availability in real time. This information allows the GOE to instantly assess its facilities' stock levels, data which can inform the redistribution of RTK between facilities as necessary to avoid stock-outs.

- b. We understand that Uganda, which has a very complex supply chain, has been further divided between CDC and USAID in terms of USG responsibility. Can you describe how this arrangement works in practice? What role does OGAC play in coordinating USAID's and CDC's efforts?

In Uganda, PEPFAR provides antiretroviral medicines (ARVs) for one million people living with HIV, 67 percent of whom are served in the public sector. While PEPFAR has historically covered the full HIV commodity need for the private and private not-

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for-profit (PNFP) sectors, since its 2015 Country Operational Plan (COP), in Uganda, PEPFAR has increased its commodity investments in the public sector by 40 percent. This makes commodities the largest share of PEPFAR's investments in the country. For the long-term success and sustainability of Uganda's HIV/AIDS response, the Government of Uganda (GOU) must increase its own HIV/AIDS investments, including to ensure there is a stable supply of ARVs, alongside the ongoing support from PEPFAR and the Global Fund (GF).

Earlier this year, S/GAC conducted an oversight visit to Uganda to discuss the supply chain system, GOU contributions, and the projected gaps in commodities. The S/GAC Chair worked with the PEPFAR Uganda team, the GF, key ministry of health officials, and specialists from Medical Access Uganda Limited (MAUL), Joint Medical Stores (JMS), and National Medical Stores (NMS) on a plan to address the most recent commodity gaps and ensure there will be sufficient ARV availability in the public sector to support COP 2018 implementation.

With U.S. government support, there have been major improvements in the country's supply chain performance over the past year. An affordable and effective supply chain system is critical for the achievement of the 90-90-90 UNAIDS targets and sustained epidemic control. In Uganda, the supply chain system is rationalized across three warehouses with regard to HIV-related commodities: NMS, which caters for the public sector and is funded by GOU and the GF; JMS/ PSM, which supports the PNFP sector in USAID-supported regions; and MAUL, which supports the PNFP sector in CDC-supported regions.

In addition to providing direct assistance for the procurement of ARVs and other HIV-related commodities, the U.S. government supports above-site supply chain investments through USAID, CDC, and PEPFAR implementing partners (IPs). The bulk of PEPFAR's above-site system investments in the supply chain in Uganda are implemented through an interagency partner - Uganda Health Supply Chain (UHSC), which is directly managed by USAID.

The UHSC project activities are implemented at the national level with central government, non-governmental institutions, and in all 126 districts where PEPFAR projects are implemented to support supply chain strengthening approaches and tools. At the national level, CDC provides supply chain human resource support to Ministry of Health/AIDS Control Program (MOH/ACP) through the embedded technical assistance of one supply chain specialist. This specialist helps strengthen the link between ACP, NMS, MAUL, Pharmacy division/Quantification and Procurement

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Planning Unit (QPPU) and Regional IPs in order to address national and decentralized level supply chain issues.

S/GAC is committed to ensuring that Ugandans in the greatest need have access to key HIV-related commodities. We will continue to regularly assess this issue during quarterly and weekly check-in discussions between the PEPFAR interagency field team. Additionally, the PEPFAR Coordinator and Deputy Coordinator in Uganda will continue to ensure the year-long roadmap for improving access to commodities, which was developed during the COP 2018 discussions, is on track and immediately notify the Uganda Chair and Country Lead of any areas of concern.